**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE MEDICINAL PRODUCT

Pritor 20 mg tablets

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20 mg telmisartan.

Excipients: Each tablet contains 84 mg sorbitol (E420).

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Tablet

White round tablets engraved with the code number '50H' on one side and the company logo on the other side.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Treatment of essential hypertension in adults.

### 4.2 Posology and method of administration

The usually effective dose is 40 mg once daily. Some patients may already benefit at a daily dose of 20 mg. In cases where the target blood pressure is not achieved, the dose of telmisartan can be increased to a maximum of 80 mg once daily. Alternatively, telmisartan may be used in combination with thiazide-type diuretics such as hydrochlorothiazide, which has been shown to have an additive blood pressure lowering effect with telmisartan. When considering raising the dose, it must be borne in mind that the maximum antihypertensive effect is generally attained four to eight weeks after the start of treatment (see section 5.1).
Telmisartan may be taken with or without food.

Renal impairment: No posology adjustment is required for patients with mild to moderate renal impairment. Limited experience is available in patients with severe renal impairment or haemodialysis. A lower starting dose of 20 mg is recommended in these patients (see section 4.4).

Hepatic impairment: In patients with mild to moderate hepatic impairment the posology should not exceed 40 mg once daily (see section 4.4).

Elderly
No dose adjustment is necessary for elderly patients.

Paediatric patients
Pritor is not recommended for use in children below 18 years due to a lack of data on safety and efficacy.

### 4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients (see section 6.1)

- Second and third trimesters of pregnancy (see sections 4.4 and 4.6)
- Biliary obstructive disorders
- Severe hepatic impairment

## 4.4 Special warnings and precautions for use

Pregnancy:
Angiotensin II receptor antagonists should not be initiated during pregnancy. Unless continued angiotensin II receptor antagonist therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started (see sections 4.3 and 4.6).

Hepatic impairment:
Pritor is not to be given to patients with cholestasis, biliary obstructive disorders or severe hepatic impairment (see section 4.3) since telmisartan is mostly eliminated with the bile. These patients can be expected to have reduced hepatic clearance for telmisartan. Pritor should be used only with caution in patients with mild to moderate hepatic impairment.

Renovascular hypertension:
There is an increased risk of severe hypotension and renal insufficiency when patients with bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney are treated with medicinal products that affect the renin-angiotensin-aldosterone system.

Renal impairment and kidney transplantation:
When Pritor is used in patients with impaired renal function, periodic monitoring of potassium and creatinine serum levels is recommended. There is no experience regarding the administration of Pritor in patients with recent kidney transplantation.

Intravascular hypovolaemia:
Symptomatic hypotension, especially after the first dose of Pritor, may occur in patients who are volume and/or sodium depleted by vigorous diuretic therapy, dietary salt restriction, diarrhoea, or vomiting. Such conditions should be corrected before the administration of Pritor. Volume and/or sodium depletion should be corrected prior to administration of Pritor.

Dual blockade of the renin-angiotensin-aldosterone system: As a consequence of inhibiting the renin-angiotensin-aldosterone system, hypotension and changes in renal function (including acute renal failure) have been reported in susceptible individuals, especially if combining medicinal products that affect this system. Dual blockade of the renin-angiotensin-aldosterone system (e.g. by adding an ACE-inhibitor to an angiotensin II receptor antagonist) is therefore not recommended in patients with already controlled blood pressure and should be limited to individually defined cases with close monitoring of renal function.

Other conditions with stimulation of the renin-angiotensin-aldosterone system:
In patients whose vascular tone and renal function depend predominantly on the activity of the renin-angiotensin-aldosterone system (e.g. patients with severe congestive heart failure or underlying renal disease, including renal artery stenosis), treatment with medicinal products that affect this system such as telmisartan has been associated with acute hypotension, hyperazotaemia, oliguria, or rarely acute renal failure (see section 4.8).

Primary aldosteronism:
Patients with primary aldosteronism generally will not respond to antihypertensive medicinal products acting through inhibition of the renin-angiotensin system. Therefore, the use of telmisartan is not recommended.

Aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy:
As with other vasodilators, special caution is indicated in patients suffering from aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy.

Hyperkalaemia:
The use of medicinal products that affect the renin-angiotensin-aldosterone system may cause hyperkalaemia.
In the elderly, in patients with renal insufficiency, in diabetic patients, in patients concomitantly treated with other medicinal products that may increase potassium levels, and/or in patients with intercurrent events, hyperkalaemia may be fatal.

Before considering the concomitant use of medicinal products that affect the renin-angiotensin-aldosterone system, the benefit risk ratio should be evaluated.
The main risk factors for hyperkalaemia to be considered are:
- Diabetes mellitus, renal impairment, age (>70 years)
- Combination with one or more other medicinal products that affect the renin-angiotensin-aldosterone system and/or potassium supplements. Medicinal products or therapeutic classes of medicinal products that may provoke hyperkalaemia are salt substitutes containing potassium, potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, non steroidal anti-inflammatory medicinal products (NSAIDs, including selective COX-2 inhibitors), heparin, immunosuppressives (cyclosporin or tacrolimus), and trimethoprim.
- Intercurrent events, in particular dehydratation, acute cardiac decompensation, metabolic acidosis, worsening of renal function, sudden worsening of the renal condition (e.g. infectious diseases), cellular lysis (e.g. acute limb ischemia, rhabdomyolysis, extend trauma).

Close monitoring of serum potassium in at risk patients is recommended (see section 4.5).

Sorbitol:
This medicinal product contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take Pritor.

Ethnic differences:
As observed for angiotensin converting enzyme inhibitors, telmisartan and the other angiotensin II receptor antagonists are apparently less effective in lowering blood pressure in black people than in non-blacks, possibly because of higher prevalence of low-renin states in the black hypertensive population.

Other:
As with any antihypertensive agent, excessive reduction of blood pressure in patients with ischaemic cardiopathy or ischaemic cardiovascular disease could result in a myocardial infarction or stroke.

## 4.5 Interaction with other medicinal products and other forms of interaction

Interaction studies have only been performed in adults.

As with others drugs acting on the renin-angiotensin-aldosterone system, telmisartan may provoke hyperkalaemia (see section 4.4). The risk may increase in case of treatment combination with other medicinal products that may also provoke hyperkalaemia (salt substitutes containing potassium, potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, non steroidal anti-inflammatory medicinal products (NSAIDs, including selective COX-2 inhibitors), heparin, immunosuppressives (cyclosporin or tacrolimus), and trimethoprim).

The occurrence of hyperkalaemia depends on associated risk factors. The risk is increased in case of the above-mentioned treatment combinations. The risk is particularly high in combination with potassium sparing-diuretics, and when combined with salt substitutes containing potassium. A combination with ACE inhibitors or NSAIDs, for example, presents a lesser risk provided that precautions for use are strictly followed.

*Concomitant use not recommended*

Potassium sparing diuretics or potassium supplements:
Angiotensin II receptor antagonists such as telmisartan, attenuate diuretic induced potassium loss. Potassium sparing diuretics e.g. spirinolactone, eplerenone, triamterene, or amiloride, potassium supplements, or potassium-containing salt substitutes may lead to a significant increase in serum potassium. If concomitant use is indicated because of documented hypokalaemia, they should be used with caution and with frequent monitoring of serum potassium.

Lithium*:*
Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with angiotensin converting enzyme inhibitors, and with angiotensin II receptor antagonists, including telmisartan. If use of the combination proves necessary, careful monitoring of serum lithium levels is recommended.

*Concomitant use requiring caution*

Non-steroidal anti-inflammatory medicinal products:
NSAIDs (i.e. acetylsalicylic acid at anti-inflammatory dosage regimens, COX-2 inhibitors and non-selective NSAIDs) may reduce the antihypertensive effect of angiotensin II receptor antagonists.
In some patients with compromised renal function (e.g. dehydrated patients or elderly patients with compromised renal function), the co-administration of angiotensin II receptor antagonists and agents that inhibit cyclo-oxygenase may result in further deterioration of renal function, including possible acute renal failure, which is usually reversible. Therefore, the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy and periodically thereafter.

In one study the co-administration of telmisartan and ramipril led to an increase of up to 2.5 fold in the $AUC_{0-24}$ and $C_{max}$ of ramipril and ramiprilat. The clinical relevance of this observation is not known.

Diuretics (thiazide or loop diuretics):
Prior treatment with high dose diuretics such as furosemide (loop diuretic) and hydrochlorothiazide (thiazide diuretic) may result in volume depletion and in a risk of hypotension when initiating therapy with telmisartan.

*To be taken into account with concomitant use*

Other antihypertensive agents:
The blood pressure lowering effect of telmisartan can be increased by concomitant use of other antihypertensive medicinal products.

Based on their pharmacological properties it can be expected that the following medicinal products may potentiate the hypotensive effects of all antihypertensives including telmisartan: Baclofen, amifostine. Furthermore, orthostatic hypotension may be aggravated by alcohol, barbiturates, narcotics or antidepressants.

Corticosteroïds (systemic route):
Reduction of the antihypertensive effect.

## 4.6 Pregnancy and lactation

Pregnancy:

The use of angiotensin II receptor antagonists is not recommended during the first trimester of pregnancy (see section 4.4). The use of angiotensin II receptor antagonists is contraindicated during the second and third trimesters of pregnancy (see sections 4.3 and 4.4).

There are no adequate data from the use of Pritor in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3).

Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however a small increase in risk cannot be excluded. Whilst there is no controlled epidemiological data on the risk with angiotensin II receptor antagonists, similar risks may exist for this class of drugs. Unless continued angiotensin II receptor antagonist therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started.

Exposure to angiotensin II receptor antagonist therapy during the second and third trimesters is known to induce human fetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia). (See section 5.3).
Should exposure to angiotensin II receptor antagonists have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended.
Infants whose mothers have taken angiotensin II receptor antagonists should be closely observed for hypotension (see sections 4.3 and 4.4).

Lactation:
Because no information is available regarding the use of Pritor during breast-feeding, Pritor is not recommended and alternative treatments with better established safety profiles during breast-feeding are preferable, especially while nursing a newborn or preterm infant.

### 4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, when driving vehicles or operating machinery it should be taken into account that dizziness or drowsiness may occasionally occur when taking antihypertensive therapy.

### 4.8 Undesirable effects

The overall incidence of adverse events reported with telmisartan (41.4 %) was usually comparable to placebo (43.9 %) in placebo controlled trials. The incidence of adverse events was not dose related and showed no correlation with gender, age or race of the patients.

The adverse drug reactions listed below have been accumulated from all clinical trials including 5788 hypertensive patients treated with telmisartan.

Adverse reactions have been ranked under headings of frequency using the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Infections and infestations

| | |
|---|---|
| Rare: | Upper respiratory tract infection including pharyngitis and sinusitis |
| Not known: | Urinary tract infection including cystitis |

Blood and the lymphatic system disorders

| | |
|---|---|
| Rare: | Anaemia, thrombocytopenia |
| Not known: | Eosinophilia |

Immune system disorders

| | |
|---|---|
| Not known: | Hypersensitivity, anaphylactic reaction |

Metabolism and nutrition disorders

| | |
|---|---|
| Uncommon: | Hyperkalaemia |

Psychiatric disorders

| | |
|---|---|
| Rare: | Anxiety, depression |

Nervous system disorders

| | |
|---|---|
| Uncommon: | Syncope, insomnia |

Eye disorders

| | |
|---|---|
| Rare: | Abnormal vision |

Ear and labyrinth disorders

| | |
|---|---|
| Uncommon: | Vertigo |

Cardiac disorders

| | |
|---|---|
| Rare: | Tachycardia |
| Not known: | Bradycardia |

Vascular disorders

| | |
|---|---|
| Uncommon: | Hypotension |
| Rare: | Orthostatic hypotension |

Respiratory, thoracic and mediastinal disorders

| | |
|---|---|
| Uncommon: | Dyspnoea |

Gastrointestinal disorders

| | |
|---|---|
| Uncommon: | Abdominal pain, diarrhoea, dry mouth, dyspepsia, flatulence |
| Rare: | Stomach upset, vomiting |

Hepato-biliary disorders

| | |
|---|---|
| Rare: | Hepatic function abnormal/liver disorder |

Skin and subcutaneous tissue disorders

| | |
|---|---|
| Uncommon: | Hyperhidrosis, pruritus |
| Rare: | Erythema, angioedema, urticaria |
| Not known: | Drug eruption, toxic skin eruption, rash, eczema |

Muscoloskeletal and connective tissue disorders

| | |
|---|---|
| Uncommon: | Myalgia |
| Rare: | Arthralgia, back pain (e.g. sciatica), muscle cramps, pain in limb, weakness |
| Not known: | Tendonitis |

Renal and urinary disorders

| | |
|---|---|
| Uncommon: | Renal impairment including acute renal failure |

General disorders and administration site conditions

| | | |
|---|---|---|
| | Uncommon: | Chest pain |
| | Rare: | Influenza-like illness |
| | Not known: | Drug ineffective |

Investigations

| | |
|---|---|
| Rare: | Blood uric acid increased, blood creatinine increased, hepatic enzyme increased, blood creatine phosphokinase increased |
| Not known: | Haemoglobin decreased |

### 4.9 Overdose

There is limited information available with regard to overdose in humans.

Symptoms: The most prominent manifestations of telmisartan overdose were hypotension and tachycardia; bradycardia, dizziness, increase in serum creatinine, and acute renal failure have also been reported.

Treatment: Telmisartan is not removed by haemodialysis. The patient should be closely monitored, and the treatment should be symptomatic and supportive. Management depends on the time since ingestion and the severity of the symptoms. Suggested measures include induction of emesis and / or gastric lavage. Activated charcoal may be useful in the treatment of overdosage. Serum electrolytes and creatinine should be monitored frequently. If hypotension occurs, the patient should be placed in a supine position, with salt and volume replacement given quickly.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Angiotensin II Antagonists, plain, ATC Code: C09CA07.

Mechanism of action:
Telmisartan is an orally active and specific angiotensin II receptor (type $AT_1$) antagonist. Telmisartan displaces angiotensin II with very high affinity from its binding site at the $AT_1$ receptor subtype, which is responsible for the known actions of angiotensin II. Telmisartan does not exhibit any partial agonist activity at the $AT_1$ receptor. Telmisartan selectively binds the $AT_1$ receptor. The binding is long-lasting. Telmisartan does not show affinity for other receptors, including $AT_2$ and other less characterised AT receptors. The functional role of these receptors is not known, nor is the effect of their possible overstimulation by angiotensin II, whose levels are increased by telmisartan. Plasma aldosterone levels are decreased by telmisartan. Telmisartan does not inhibit human plasma renin or block ion channels. Telmisartan does not inhibit angiotensin converting enzyme (kininase II), the enzyme which also degrades bradykinin. Therefore it is not expected to potentiate bradykinin-mediated adverse effects.

In human, an 80 mg dose of telmisartan almost completely inhibits the angiotensin II evoked blood pressure increase. The inhibitory effect is maintained over 24 hours and still measurable up to 48 hours.

Clinical efficacy and safety:
After the first dose of telmisartan, the antihypertensive activity gradually becomes evident within 3 hours. The maximum reduction in blood pressure is generally attained 4 to 8 weeks after the start of treatment and is sustained during long-term therapy.

The antihypertensive effect persists constantly over 24 hours after dosing and includes the last 4 hours before the next dose as shown by ambulatory blood pressure measurements. This is confirmed by trough to peak ratios consistently above 80 % seen after doses of 40 and 80 mg of telmisartan in placebo controlled clinical studies. There is an apparent trend to a dose relationship to a time to recovery of baseline systolic blood pressure (SBP). In this respect data concerning diastolic blood pressure (DBP) are inconsistent.

In patients with hypertension telmisartan reduces both systolic and diastolic blood pressure without affecting pulse rate. The contribution of the medicinal product's diuretic and natriuretic effect to its hypotensive activity has still to be defined. The antihypertensive efficacy of telmisartan is comparable to that of agents representative of other classes of antihypertensive medicinal products (demonstrated in clinical trials comparing telmisartan to amlodipine, atenolol, enalapril, hydrochlorothiazide, and lisinopril).

Upon abrupt cessation of treatment with telmisartan, blood pressure gradually returns to pre-treatment values over a period of several days without evidence of rebound hypertension.

The incidence of dry cough was significantly lower in patients treated with telmisartan than in those given angiotensin converting enzyme inhibitors in clinical trials directly comparing the two antihypertensive treatments.

Beneficial effects of telmisartan on mortality and cardiovascular morbidity are currently unknown.

## 5.2 Pharmacokinetic properties

Absorption:
Absorption of telmisartan is rapid although the amount absorbed varies. The mean absolute bioavailability for telmisartan is about 50 %. When telmisartan is taken with food, the reduction in the area under the plasma concentration-time curve ($AUC_{0-\infty}$) of telmisartan varies from approximately 6 % (40 mg dose) to approximately 19 % (160 mg dose). By 3 hours after administration, plasma concentrations are similar whether telmisartan is taken fasting or with food.

Linearity/non-linearity:
The small reduction in AUC is not expected to cause a reduction in the therapeutic efficacy. There is no linear relationship between doses and plasma levels. $C_{max}$ and to a lesser extent AUC increase disproportionately at doses above 40 mg.

Distribution:
Telmisartan is largely bound to plasma protein (>99.5 %), mainly albumin and alpha-1 acid glycoprotein. The mean steady state apparent volume of distribution ($V_{dss}$) is approximately 500 l.

Metabolism:
Telmisartan is metabolised by conjugation to the glucuronide of the parent compound. No pharmacological activity has been shown for the conjugate.

Elimination:
Telmisartan is characterised by biexponential decay pharmacokinetics with a terminal elimination half-life of >20 hours. The maximum plasma concentration ($C_{max}$) and, to a smaller extent, the area under the plasma concentration-time curve (AUC), increase disproportionately with dose. There is no evidence of clinically relevant accumulation of telmisartan taken at the recommended dose. Plasma concentrations were higher in females than in males, without relevant influence on efficacy.

After oral (and intravenous) administration telmisartan is nearly exclusively excreted with the faeces, mainly as unchanged compound. Cumulative urinary excretion is <1 % of dose. Total plasma clearance ($Cl_{tot}$) is high (approximately 1,000 ml/min) compared with hepatic blood flow (about 1,500 ml/min).

*Special Populations*

Gender effects:
Differences in plasma concentrations were observed, with $C_{max}$ and AUC being approximately 3- and 2-fold higher, respectively, in females compared to males.

Elderly patients:
The pharmacokinetics of telmisartan do not differ between the elderly and those younger than 65 years.

Patients with renal impairment:
In patients with mild to moderate and severe renal impairment, doubling of plasma concentrations was observed. However, lower plasma concentrations were observed in patients with renal insufficiency undergoing dialysis. Telmisartan is highly bound to plasma protein in renal-insufficient patients and cannot be removed by dialysis. The elimination half-life is not changed in patients with renal impairment.

Patients with hepatic impairment:
Pharmacokinetic studies in patients with hepatic impairment showed an increase in absolute bioavailability up to nearly 100 %. The elimination half-life is not changed in patients with hepatic impairment.

### 5.3 Preclinical safety data

In preclinical safety studies, doses producing exposure comparable to that in the clinical therapeutic range caused reduced red cell parameters (erythrocytes, haemoglobin, haematocrit), changes in renal haemodynamics (increased blood urea nitrogen and creatinine), as well as increased serum potassium in normotensive animals. In dogs, renal tubular dilation and atrophy were observed. Gastric mucosal injury (erosion, ulcers or inflammation) also was noted in rats and dogs. These pharmacologically-mediated undesirable effects, known from preclinical studies with both angiotensin converting enzyme inhibitors and angiotensin II receptor antagonists, were prevented by oral saline supplementation.

In both species, increased plasma renin activity and hypertrophy/hyperplasia of the renal juxtaglomerular cells were observed. These changes, also a class effect of angiotensin converting enzyme inhibitors and other angiotensin II receptor antagonists, do not appear to have clinical significance.

There is no evidence of a teratogenic effect, but animal studies indicated some hazardous potential of telmisartan to the postnatal development of the offspring such as lower body weight, delayed eye opening, and higher mortality.

There was no evidence of mutagenicity and relevant clastogenic activity in *in vitro* studies and no evidence of carcinogenicity in rats and mice.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Povidone (K25)
Meglumine
Sodium hydroxide
Sorbitol (E420)
Magnesium stearate.

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

3 years

### 6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.
Store in the original package in order to protect from moisture.

### 6.5 Nature and contents of container

Aluminium/aluminium blisters (PA/PA/Al/PVC/Al). One blister contains 7 or 10 tablets.

Pack sizes: Blister with 14, 28, 30, 56, 90 or 98 tablets.

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal

No special requirements.

## 7. MARKETING AUTHORISATION HOLDER

Bayer Schering Pharma AG
13342 Berlin
Germany

## 8. MARKETING AUTHORISATION NUMBERS

EU/1/98/089/011 (14 tablets)
EU/1/98/089/012 (28 tablets)
EU/1/98/089/020 (30 tablets)
EU/1/98/089/013 (56 tablets)
EU/1/98/089/019 (90 tablets)
EU/1/98/089/014 (98 tablets)

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 December 1998
Date of last renewal: 11 December 2008

## 10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency (EMEA) http://www.emea.europa.eu/.

## 1. NAME OF THE MEDICINAL PRODUCT

Pritor 40 mg tablets

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 40 mg telmisartan.

Excipients: Each tablet contains 169 mg sorbitol (E420).

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Tablet

White oblong tablets engraved with the code number '51H' on one side.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Treatment of essential hypertension in adults.

### 4.2 Posology and method of administration

The usually effective dose is 40 mg once daily. Some patients may already benefit at a daily dose of 20 mg. In cases where the target blood pressure is not achieved, the dose of telmisartan can be increased to a maximum of 80 mg once daily. Alternatively, telmisartan may be used in combination with thiazide-type diuretics such as hydrochlorothiazide, which has been shown to have an additive blood pressure lowering effect with telmisartan. When considering raising the dose, it must be borne in mind that the maximum antihypertensive effect is generally attained four to eight weeks after the start of treatment (see section 5.1).
Telmisartan may be taken with or without food.

Renal impairment: No posology adjustment is required for patients with mild to moderate renal impairment. Limited experience is available in patients with severe renal impairment or haemodialysis. A lower starting dose of 20 mg is recommended in these patients (see section 4.4).

Hepatic impairment: In patients with mild to moderate hepatic impairment the posology should not exceed 40 mg once daily (see section 4.4).

Elderly
No dose adjustment is necessary for elderly patients.

Paediatric patients
Pritor is not recommended for use in children below 18 years due to a lack of data on safety and efficacy.

### 4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients (see section 6.1)
- Second and third trimesters of pregnancy (see sections 4.4 and 4.6)

- Biliary obstructive disorders
- Severe hepatic impairment

## 4.4 Special warnings and precautions for use

Pregnancy:
Angiotensin II receptor antagonists should not be initiated during pregnancy. Unless continued angiotensin II receptor antagonist therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started (see sections 4.3 and 4.6).

Hepatic impairment:
Pritor is not to be given to patients with cholestasis, biliary obstructive disorders or severe hepatic impairment (see section 4.3) since telmisartan is mostly eliminated with the bile. These patients can be expected to have reduced hepatic clearance for telmisartan. Pritor should be used only with caution in patients with mild to moderate hepatic impairment.

Renovascular hypertension:
There is an increased risk of severe hypotension and renal insufficiency when patients with bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney are treated with medicinal products that affect the renin-angiotensin-aldosterone system.

Renal impairment and kidney transplantation:
When Pritor is used in patients with impaired renal function, periodic monitoring of potassium and creatinine serum levels is recommended. There is no experience regarding the administration of Pritor in patients with recent kidney transplantation.

Intravascular hypovolaemia:
Symptomatic hypotension, especially after the first dose of Pritor, may occur in patients who are volume and/or sodium depleted by vigorous diuretic therapy, dietary salt restriction, diarrhoea, or vomiting. Such conditions should be corrected before the administration of Pritor. Volume and/or sodium depletion should be corrected prior to administration of Pritor.

Dual blockade of the renin-angiotensin-aldosterone system: As a consequence of inhibiting the renin-angiotensin-aldosterone system, hypotension and changes in renal function (including acute renal failure) have been reported in susceptible individuals, especially if combining medicinal products that affect this system. Dual blockade of the renin-angiotensin-aldosterone system (e.g. by adding an ACE-inhibitor to an angiotensin II receptor antagonist) is therefore not recommended in patients with already controlled blood pressure and should be limited to individually defined cases with close monitoring of renal function.

Other conditions with stimulation of the renin-angiotensin-aldosterone system:
In patients whose vascular tone and renal function depend predominantly on the activity of the renin-angiotensin-aldosterone system (e.g. patients with severe congestive heart failure or underlying renal disease, including renal artery stenosis), treatment with medicinal products that affect this system such as telmisartan, has been associated with acute hypotension, hyperazotaemia, oliguria, or rarely acute renal failure (see section 4.8).

Primary aldosteronism:
Patients with primary aldosteronism generally will not respond to antihypertensive medicinal products acting through inhibition of the renin-angiotensin system. Therefore, the use of telmisartan is not recommended.

Aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy:

As with other vasodilators, special caution is indicated in patients suffering from aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy.

Hyperkalaemia:
The use of medicinal products that affect the renin-angiotensin-aldosterone system may cause hyperkalaemia.
In the elderly, in patients with renal insufficiency, in diabetic patients, in patients concomitantly treated with other medicinal products that may increase potassium levels, and/or in patients with intercurrent events, hyperkalaemia may be fatal.

Before considering the concomitant use of medicinal products that affect the renin-angiotensin-aldosterone system, the benefit risk ratio should be evaluated.
The main risk factors for hyperkalaemia to be considered are:
- Diabetes mellitus, renal impairment, age (>70 years)
- Combination with one or more other medicinal products that affect the renin-angiotensin-aldosterone system and/or potassium supplements. Medicinal products or therapeutic classes of medicinal products that may provoke hyperkalaemia are salt substitutes containing potassium, potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, non steroidal anti-inflammatory medicinal products (NSAIDs, including selective COX-2 inhibitors), heparin, immunosuppressives (cyclosporin or tacrolimus), and trimethoprim.
- Intercurrent events, in particular dehydratation, acute cardiac decompensation, metabolic acidosis, worsening of renal function, sudden worsening of the renal condition (e.g. infectious diseases), cellular lysis (e.g. acute limb ischemia, rhabdomyolysis, extend trauma).

Close monitoring of serum potassium in at risk patients is recommended (see section 4.5).

Sorbitol:
This medicinal product contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take Pritor.

Ethnic differences:
As observed for angiotensin converting enzyme inhibitors, telmisartan and the other angiotensin II receptor antagonists are apparently less effective in lowering blood pressure in black people than in non-blacks, possibly because of higher prevalence of low-renin states in the black hypertensive population.

Other:
As with any antihypertensive agent, excessive reduction of blood pressure in patients with ischaemic cardiopathy or ischaemic cardiovascular disease could result in a myocardial infarction or stroke.

## 4.5 Interaction with other medicinal products and other forms of interaction

Interaction studies have only been performed in adults.

As with others drugs acting on the renin-angiotensin-aldosterone system, telmisartan may provoke hyperkalaemia (see section 4.4). The risk may increase in case of treatment combination with other medicinal products that may also provoke hyperkalaemia (salt substitutes containing potassium, potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, non steroidal anti-inflammatory medicinal products (NSAIDs, including selective COX-2 inhibitors), heparin, immunosuppressives (cyclosporin or tacrolimus), and trimethoprim).

The occurrence of hyperkalaemia depends on associated risk factors. The risk is increased in case of the above-mentioned treatment combinations. The risk is particularly high in combination with potassium sparing-diuretics, and when combined with salt substitutes containing potassium. A combination with ACE inhibitors or NSAIDs, for example, presents a lesser risk provided that precautions for use are strictly followed.

*Concomitant use not recommended*

Potassium sparing diuretics or potassium supplements:
Angiotensin II receptor antagonists such as telmisartan, attenuate diuretic induced potassium loss. Potassium sparing diuretics e.g. spirinolactone, eplerenone, triamterene, or amiloride, potassium supplements, or potassium-containing salt substitutes may lead to a significant increase in serum potassium. If concomitant use is indicated because of documented hypokalaemia they should be used with caution and with frequent monitoring of serum potassium.

Lithium:
Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with angiotensin converting enzyme inhibitors, and with angiotensin II receptor antagonists, including telmisartan. If use of the combination proves necessary, careful monitoring of serum lithium levels is recommended.

*Concomitant use requiring caution*

Non-steroidal anti-inflammatory medicinal products:
NSAIDs (i.e. acetylsalicylic acid at anti-inflammatory dosage regimens, COX-2 inhibitors and non-selective NSAIDs) may reduce the antihypertensive effect of angiotensin II receptor antagonists.
In some patients with compromised renal function (e.g. dehydrated patients or elderly patients with compromised renal function), the co-administration of angiotensin II receptor antagonists and agents that inhibit cyclo-oxygenase may result in further deterioration of renal function, including possible acute renal failure, which is usually reversible. Therefore, the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy and periodically thereafter.

In one study the co-administration of telmisartan and ramipril led to an increase of up to 2.5 fold in the $AUC_{0-24}$ and $C_{max}$ of ramipril and ramiprilat. The clinical relevance of this observation is not known.

Diuretics (thiazide or loop diuretics):
Prior treatment with high dose diuretics such as furosemide (loop diuretic) and hydrochlorothiazide (thiazide diuretic) may result in volume depletion and in a risk of hypotension when initiating therapy with telmisartan.

*To be taken into account with concomitant use*

Other antihypertensive agents:
The blood pressure lowering effect of telmisartan can be increased by concomitant use of other antihypertensive medicinal products.

Based on their pharmacological properties it can be expected that the following medicinal products may potentiate the hypotensive effects of all antihypertensives including telmisartan: Baclofen, amifostine. Furthermore, orthostatic hypotension may be aggravated by alcohol, barbiturates, narcotics or antidepressants.

Corticosteroïds (systemic route):
Reduction of the antihypertensive effect.

## 4.6 Pregnancy and lactation

Pregnancy:

The use of angiotensin II receptor antagonists is not recommended during the first trimester of pregnancy (see section 4.4). The use of angiotensin II receptor antagonists is contraindicated during the second and third trimesters of pregnancy (see sections 4.3 and 4.4).

There are no adequate data from the use of Pritor in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3).

Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however a small increase in risk cannot be excluded. Whilst there is no controlled epidemiological data on the risk with angiotensin II receptor antagonists, similar risks may exist for this class of drugs. Unless continued angiotensin II receptor antagonist therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started.

Exposure to angiotensin II receptor antagonist therapy during the second and third trimesters is known to induce human fetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia). (See section 5.3).
Should exposure to angiotensin II receptor antagonists have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended.
Infants whose mothers have taken angiotensin II receptor antagonists should be closely observed for hypotension (see sections 4.3 and 4.4).

Lactation:
Because no information is available regarding the use of Pritor during breast-feeding, Pritor is not recommended and alternative treatments with better established safety profiles during breast-feeding are preferable, especially while nursing a newborn or preterm infant.

### 4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, when driving vehicles or operating machinery it should be taken into account that dizziness or drowsiness may occasionally occur when taking antihypertensive therapy.

### 4.8 Undesirable effects

The overall incidence of adverse events reported with telmisartan (41.4 %) was usually comparable to placebo (43.9 %) in placebo controlled trials. The incidence of adverse events was not dose related and showed no correlation with gender, age or race of the patients.

The adverse drug reactions listed below have been accumulated from all clinical trials including 5788 hypertensive patients treated with telmisartan.

Adverse reactions have been ranked under headings of frequency using the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Infections and infestations

| | |
|---|---|
| Rare: | Upper respiratory tract infection including pharyngitis and sinusitis |
| Not known: | Urinary tract infection including cystitis |

Blood and the lymphatic system disorders

| | |
|---|---|
| Rare: | Anaemia, thrombocytopenia |
| Not known: | Eosinophilia |

Immune system disorders

| | |
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| Not known: | Hypersensitivity, anaphylactic reaction |

Metabolism and nutrition disorders

| | |
|---|---|
| Uncommon: | Hyperkalaemia |

Psychiatric disorders

| | |
|---|---|
| Rare: | Anxiety, depression |

Nervous system disorders

| | |
|---|---|
| Uncommon: | Syncope, insomnia |

Eye disorders

| | |
|---|---|
| Rare: | Abnormal vision |

Ear and labyrinth disorders

| | |
|---|---|
| Uncommon: | Vertigo |

Cardiac disorders

| | |
|---|---|
| Rare: | Tachycardia |
| Not known: | Bradycardia |

Vascular disorders

| | |
|---|---|
| Uncommon: | Hypotension |
| Rare: | Orthostatic hypotension |

Respiratory, thoracic and mediastinal disorders

| | |
|---|---|
| Uncommon: | Dyspnoea |

Gastrointestinal disorders

| | |
|---|---|
| Uncommon: | Abdominal pain, diarrhoea, dry mouth, dyspepsia, flatulence |
| Rare: | Stomach upset, vomiting |

Hepato-biliary disorders

| | |
|---|---|
| Rare: | Hepatic function abnormal/liver disorder |

Skin and subcutaneous tissue disorders

| | |
|---|---|
| Uncommon: | Hyperhidrosis, pruritus |
| Rare: | Erythema, angioedema, urticaria |
| Not known: | Drug eruption, toxic skin eruption, rash, eczema |

Muscoloskeletal and connective tissue disorders

| | |
|---|---|
| Uncommon: | Myalgia |
| Rare: | Arthralgia, back pain (e.g. sciatica), muscle cramps, pain in limb, weakness |
| Not known: | Tendonitis |

Renal and urinary disorders

| | |
|---|---|
| Uncommon: | Renal impairment including acute renal failure |

General disorders and administration site conditions

| | |
|---|---|
| Uncommon: | Chest pain |
| Rare: | Influenza-like illness |
| Not known: | Drug ineffective |

Investigations

| | |
|---|---|
| Rare: | Blood uric acid increased, blood creatinine increased, hepatic enzyme increased, blood creatine phosphokinase increased |
| Not known: | Haemoglobin decreased |

### 4.9 Overdose

There is limited information available with regard to overdose in humans.

Symptoms: The most prominent manifestations of telmisartan overdose were hypotension and tachycardia; bradycardia, dizziness, increase in serum creatinine, and acute renal failure have also been reported.

Treatment: Telmisartan is not removed by haemodialysis. The patient should be closely monitored, and the treatment should be symptomatic and supportive. Management depends on the time since ingestion and the severity of the symptoms. Suggested measures include induction of emesis and / or gastric lavage. Activated charcoal may be useful in the treatment of overdosage. Serum electrolytes and creatinine should be monitored frequently. If hypotension occurs, the patient should be placed in a supine position, with salt and volume replacement given quickly.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Angiotensin II Antagonists, plain, ATC Code: C09CA07.

Mechanism of action:
Telmisartan is an orally active and specific angiotensin II receptor (type $AT_1$) antagonist. Telmisartan displaces angiotensin II with very high affinity from its binding site at the $AT_1$ receptor subtype, which is responsible for the known actions of angiotensin II. Telmisartan does not exhibit any partial agonist activity at the $AT_1$ receptor. Telmisartan selectively binds the $AT_1$ receptor. The binding is long-lasting. Telmisartan does not show affinity for other receptors, including $AT_2$ and other less characterised AT receptors. The functional role of these receptors is not known, nor is the effect of their possible overstimulation by angiotensin II, whose levels are increased by telmisartan. Plasma aldosterone levels are decreased by telmisartan. Telmisartan does not inhibit human plasma renin or block ion channels. Telmisartan does not inhibit angiotensin converting enzyme (kininase II), the enzyme which also degrades bradykinin. Therefore it is not expected to potentiate bradykinin-mediated adverse effects.

In human, an 80 mg dose of telmisartan almost completely inhibits the angiotensin II evoked blood pressure increase. The inhibitory effect is maintained over 24 hours and still measurable up to 48 hours.

Clinical efficacy and safety:
After the first dose of telmisartan, the antihypertensive activity gradually becomes evident within 3 hours. The maximum reduction in blood pressure is generally attained 4 to 8 weeks after the start of treatment and is sustained during long-term therapy.

The antihypertensive effect persists constantly over 24 hours after dosing and includes the last 4 hours before the next dose as shown by ambulatory blood pressure measurements. This is confirmed by trough to peak ratios consistently above 80 % seen after doses of 40 and 80 mg of telmisartan in placebo controlled clinical studies. There is an apparent trend to a dose relationship to a time to recovery of baseline systolic blood pressure (SBP). In this respect data concerning diastolic blood pressure (DBP) are inconsistent.

In patients with hypertension telmisartan reduces both systolic and diastolic blood pressure without affecting pulse rate. The contribution of the medicinal product's diuretic and natriuretic effect to its hypotensive activity has still to be defined. The antihypertensive efficacy of telmisartan is comparable to that of agents representative of other classes of antihypertensive medicinal products (demonstrated in clinical trials comparing telmisartan to amlodipine, atenolol, enalapril, hydrochlorothiazide, and lisinopril).

Upon abrupt cessation of treatment with telmisartan, blood pressure gradually returns to pre-treatment values over a period of several days without evidence of rebound hypertension.

The incidence of dry cough was significantly lower in patients treated with telmisartan than in those given angiotensin converting enzyme inhibitors in clinical trials directly comparing the two antihypertensive treatments.

Beneficial effects of telmisartan on mortality and cardiovascular morbidity are currently unknown.

## 5.2 Pharmacokinetic properties

Absorption:
Absorption of telmisartan is rapid although the amount absorbed varies. The mean absolute bioavailability for telmisartan is about 50 %. When telmisartan is taken with food, the reduction in the area under the plasma concentration-time curve ($AUC_{0-\infty}$) of telmisartan varies from approximately 6 % (40 mg dose) to approximately 19 % (160 mg dose). By 3 hours after administration, plasma concentrations are similar whether telmisartan is taken fasting or with food.

Linearity/non-linearity:
The small reduction in AUC is not expected to cause a reduction in the therapeutic efficacy. There is no linear relationship between doses and plasma levels. $C_{max}$ and to a lesser extent AUC increase disproportionately at doses above 40 mg.

Distribution:
Telmisartan is largely bound to plasma protein (>99.5 %), mainly albumin and alpha-1 acid glycoprotein. The mean steady state apparent volume of distribution ($V_{dss}$) is approximately 500 l.

Metabolism:
Telmisartan is metabolised by conjugation to the glucuronide of the parent compound. No pharmacological activity has been shown for the conjugate.

Elimination:
Telmisartan is characterised by biexponential decay pharmacokinetics with a terminal elimination half-life of >20 hours. The maximum plasma concentration ($C_{max}$) and, to a smaller extent, the area

under the plasma concentration-time curve (AUC), increase disproportionately with dose. There is no evidence of clinically relevant accumulation of telmisartan taken at the recommended dose. Plasma concentrations were higher in females than in males, without relevant influence on efficacy.

After oral (and intravenous) administration telmisartan is nearly exclusively excreted with the faeces, mainly as unchanged compound. Cumulative urinary excretion is <1 % of dose. Total plasma clearance ($Cl_{tot}$) is high (approximately 1,000 ml/min) compared with hepatic blood flow (about 1,500 ml/min).

*Special Populations*

Gender effects:
Differences in plasma concentrations were observed, with $C_{max}$ and AUC being approximately 3- and 2-fold higher, respectively, in females compared to males.

Elderly patients:
The pharmacokinetics of telmisartan do not differ between the elderly and those younger than 65 years.

Patients with renal impairment:
In patients with mild to moderate and severe renal impairment, doubling of plasma concentrations was observed. However, lower plasma concentrations were observed in patients with renal insufficiency undergoing dialysis. Telmisartan is highly bound to plasma protein in renal-insufficient patients and cannot be removed by dialysis. The elimination half-life is not changed in patients with renal impairment.

Patients with hepatic impairment:
Pharmacokinetic studies in patients with hepatic impairment showed an increase in absolute bioavailability up to nearly 100 %. The elimination half-life is not changed in patients with hepatic impairment.

### 5.3 Preclinical safety data

In preclinical safety studies, doses producing exposure comparable to that in the clinical therapeutic range caused reduced red cell parameters (erythrocytes, haemoglobin, haematocrit), changes in renal haemodynamics (increased blood urea nitrogen and creatinine), as well as increased serum potassium in normotensive animals. In dogs, renal tubular dilation and atrophy were observed. Gastric mucosal injury (erosion, ulcers or inflammation) also was noted in rats and dogs. These pharmacologically-mediated undesirable effects, known from preclinical studies with both angiotensin converting enzyme inhibitors and angiotensin II receptor antagonists, were prevented by oral saline supplementation.

In both species, increased plasma renin activity and hypertrophy/hyperplasia of the renal juxtaglomerular cells were observed. These changes, also a class effect of angiotensin converting enzyme inhibitors and other angiotensin II receptor antagonists, do not appear to have clinical significance.

There is no evidence of a teratogenic effect, but animal studies indicated some hazardous potential of telmisartan to the postnatal development of the offspring such as lower body weight, delayed eye opening, and higher mortality.

There was no evidence of mutagenicity and relevant clastogenic activity in *in vitro* studies and no evidence of carcinogenicity in rats and mice.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Povidone (K25)
Meglumine
Sodium hydroxide
Sorbitol (E420)
Magnesium stearate.

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

4 years

### 6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.
Store in the original package in order to protect from moisture.

### 6.5 Nature and contents of container

Aluminium/aluminium blisters (PA/PA/Al/PVC/Al). One blister contains 7 or 10 tablets.

Pack sizes: Blister with 14, 28, 30, 56, 90, 98 or 280 tablets or perforated unit dose blisters with 28 x 1 tablets.

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal

No special requirements.

## 7. MARKETING AUTHORISATION HOLDER

Bayer Schering Pharma AG
13342 Berlin
Germany

## 8. MARKETING AUTHORISATION NUMBERS

EU/1/98/089/001 (14 tablets)
EU/1/98/089/002 (28 tablets)
EU/1/98/089/021 (30 tablets)
EU/1/98/089/003 (56 tablets)
EU/1/98/089/017 (90 tablets)
EU/1/98/089/004 (98 tablets)
EU/1/98/089/005 (280 tablets)
EU/1/98/089/015 (28 x 1 tablets)

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 December 1998
Date of last renewal: 11 December 2008

## 10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency (EMEA) http://www.emea.europa.eu/.

## 1. NAME OF THE MEDICINAL PRODUCT

Pritor 80 mg tablets

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 80 mg telmisartan.

Excipients: Each tablet contains 338 mg sorbitol (E420).

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Tablet

White oblong tablets engraved with the code number '52H' on one side.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Treatment of essential hypertension in adults.

### 4.2 Posology and method of administration

The usually effective dose is 40 mg once daily. Some patients may already benefit at a daily dose of 20 mg. In cases where the target blood pressure is not achieved, the dose of telmisartan can be increased to a maximum of 80 mg once daily. Alternatively, telmisartan may be used in combination with thiazide-type diuretics such as hydrochlorothiazide, which has been shown to have an additive blood pressure lowering effect with telmisartan. When considering raising the dose, it must be borne in mind that the maximum antihypertensive effect is generally attained four to eight weeks after the start of treatment (see section 5.1).
Telmisartan may be taken with or without food.

Renal impairment: No posology adjustment is required for patients with mild to moderate renal impairment. Limited experience is available in patients with severe renal impairment or haemodialysis. A lower starting dose of 20 mg is recommended in these patients (see section 4.4).

Hepatic impairment: In patients with mild to moderate hepatic impairment the posology should not exceed 40 mg once daily (see section 4.4).

Elderly
No dose adjustment is necessary for elderly patients.

Paediatric patients:
Pritor is not recommended for use in children below 18 years due to a lack of data on safety and efficacy.

### 4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients (see section 6.1)
- Second and third trimesters of pregnancy (see sections 4.4 and 4.6)

- Biliary obstructive disorders
- Severe hepatic impairment

## 4.4 Special warnings and precautions for use

Pregnancy:
Angiotensin II receptor antagonists should not be initiated during pregnancy. Unless continued angiotensin II receptor antagonist therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started (see sections 4.3 and 4.6).

Hepatic impairment:
Pritor is not to be given to patients with cholestasis, biliary obstructive disorders or severe hepatic impairment (see section 4.3) since telmisartan is mostly eliminated with the bile. These patients can be expected to have reduced hepatic clearance for telmisartan. Pritor should be used only with caution in patients with mild to moderate hepatic impairment.

Renovascular hypertension:
There is an increased risk of severe hypotension and renal insufficiency when patients with bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney are treated with medicinal products that affect the renin-angiotensin-aldosterone system.

Renal impairment and kidney transplantation:
When Pritor is used in patients with impaired renal function, periodic monitoring of potassium and creatinine serum levels is recommended. There is no experience regarding the administration of Pritor in patients with recent kidney transplantation.

Intravascular hypovolaemia:
Symptomatic hypotension, especially after the first dose of Pritor, may occur in patients who are volume and/or sodium depleted by vigorous diuretic therapy, dietary salt restriction, diarrhoea, or vomiting. Such conditions should be corrected before the administration of Pritor. Volume and/or sodium depletion should be corrected prior to administration of Pritor.

Dual blockade of the renin-angiotensin-aldosterone system: As a consequence of inhibiting the renin-angiotensin-aldosterone system, hypotension and changes in renal function (including acute renal failure) have been reported in susceptible individuals, especially if combining medicinal products that affect this system. Dual blockade of the renin-angiotensin-aldosterone system (e.g. by adding an ACE-inhibitor to an angiotensin II receptor antagonist) is therefore not recommended in patients with already controlled blood pressure and should be limited to individually defined cases with close monitoring of renal function.

Other conditions with stimulation of the renin-angiotensin-aldosterone system:
In patients whose vascular tone and renal function depend predominantly on the activity of the renin-angiotensin-aldosterone system (e.g. patients with severe congestive heart failure or underlying renal disease, including renal artery stenosis), treatment with medicinal products that affect this system such as telmisartan, has been associated with acute hypotension, hyperazotaemia, oliguria, or rarely acute renal failure (see section 4.8).

Primary aldosteronism:
Patients with primary aldosteronism generally will not respond to antihypertensive medicinal products acting through inhibition of the renin-angiotensin system. Therefore, the use of telmisartan is not recommended.

Aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy:

As with other vasodilators, special caution is indicated in patients suffering from aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy.

Hyperkalaemia:
The use of medicinal products that affect the renin-angiotensin-aldosterone system may cause hyperkalaemia.
In the elderly, in patients with renal insufficiency, in diabetic patients, in patients concomitantly treated with other medicinal products that may increase potassium levels, and/or in patients with intercurrent events, hyperkalaemia may be fatal.

Before considering the concomitant use of medicinal products that affect the renin-angiotensin-aldosterone system, the benefit risk ratio should be evaluated.
The main risk factors for hyperkalaemia to be considered are:
- Diabetes mellitus, renal impairment, age (>70 years)
- Combination with one or more other medicinal products that affect the renin-angiotensin-aldosterone system and/or potassium supplements. Medicinal products or therapeutic classes of medicinal products that may provoke hyperkalaemia are salt substitutes containing potassium, potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, non steroidal anti-inflammatory drugs (NSAIDs, including selective COX-2 inhibitors), heparin, immunosuppressives (cyclosporin or tacrolimus), and trimethoprim.
- Intercurrent events, in particular dehydratation, acute cardiac decompensation, metabolic acidosis, worsening of renal function, sudden worsening of the renal condition (e.g. infectious diseases), cellular lysis (e.g. acute limb ischemia, rhabdomyolysis, extend trauma).

Close monitoring of serum potassium in at risk patients is recommended (see section 4.5).

Sorbitol:
This medicinal product contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take Pritor.

Ethnic differences:
As observed for angiotensin converting enzyme inhibitors, telmisartan and the other angiotensin II receptor antagonists are apparently less effective in lowering blood pressure in black people than in non-blacks, possibly because of higher prevalence of low-renin states in the black hypertensive population.

Other:
As with any antihypertensive agent, excessive reduction of blood pressure in patients with ischaemic cardiopathy or ischaemic cardiovascular disease could result in a myocardial infarction or stroke.

## 4.5 Interaction with other medicinal products and other forms of interaction

Interaction studies have only been performed in adults.

As with others drugs acting on the renin-angiotensin-aldosterone system, telmisartan may provoke hyperkalaemia (see section 4.4). The risk may increase in case of treatment combination with other medicinal products that may also provoke hyperkalaemia (salt substitutes containing potassium, potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, non steroidal anti-inflammatory medicinal products (NSAIDs, including selective COX-2 inhibitors), heparin, immunosuppressives (cyclosporin or tacrolimus), and trimethoprim).

The occurrence of hyperkalaemia depends on associated risk factors. The risk is increased in case of the above-mentioned treatment combinations. The risk is particularly high in combination with potassium sparing-diuretics, and when combined with salt substitutes containing potassium. A combination with ACE inhibitors or NSAIDs, for example, presents a lesser risk provided that precautions for use are strictly followed.

*Concomitant use not recommended*

Potassium sparing diuretics or potassium supplements:
Angiotensin II receptor antagonists attenuate diuretic induced potassium loss. Potassium sparing diuretics e.g. spirinolactone, eplerenone, triamterene, or amiloride, potassium supplements, or potassium-containing salt substitutes may lead to a significant increase in serum potassium. If concomitant use is indicated because of documented hypokalaemia they should be used with caution and with frequent monitoring of serum potassium.

Lithium:
Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with angiotensin converting enzyme inhibitors, and with angiotensin II receptor antagonists, including telmisartan. If use of the combination proves necessary, careful monitoring of serum lithium levels is recommended.

*Concomitant use requiring caution*

Non-steroidal anti-inflammatory medicinal products:
NSAIDs (i.e. acetylsalicylic acid at anti-inflammatory dosage regimens, COX-2 inhibitors and non-selective NSAIDs) may reduce the antihypertensive effect of angiotensin II receptor antagonists.
In some patients with compromised renal function (e.g. dehydrated patients or elderly patients with compromised renal function), the co-administration of angiotensin II receptor antagonists and agents that inhibit cyclo-oxygenase may result in further deterioration of renal function, including possible acute renal failure, which is usually reversible. Therefore, the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy and periodically thereafter.

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Prior treatment with high dose diuretics such as furosemide (loop diuretic) and hydrochlorothiazide (thiazide diuretic) may result in volume depletion and in a risk of hypotension when initiating therapy with telmisartan.

*To be taken into account with concomitant use*

Other antihypertensive agents:
The blood pressure lowering effect of telmisartan can be increased by concomitant use of other antihypertensive medicinal products.

Based on their pharmacological properties it can be expected that the following medicinal products may potentiate the hypotensive effects of all antihypertensives including telmisartan: Baclofen, amifostine. Furthermore, orthostatic hypotension may be aggravated by alcohol, barbiturates, narcotics or antidepressants.

Corticosteroïds (systemic route):
Reduction of the antihypertensive effect.

## 4.6 Pregnancy and lactation

Pregnancy:

The use of angiotensin II receptor antagonists is not recommended during the first trimester of pregnancy (see section 4.4). The use of angiotensin II receptor antagonists is contraindicated during the second and third trimesters of pregnancy (see sections 4.3 and 4.4).

There are no adequate data from the use of Pritor in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3).

Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however a small increase in risk cannot be excluded. Whilst there is no controlled epidemiological data on the risk with angiotensin II receptor antagonists, similar risks may exist for this class of drugs. Unless continued angiotensin II receptor antagonist therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started.

Exposure to angiotensin II receptor antagonist therapy during the second and third trimesters is known to induce human fetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia). (See section 5.3).
Should exposure to angiotensin II receptor antagonists have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended.
Infants whose mothers have taken angiotensin II receptor antagonists should be closely observed for hypotension (see sections 4.3 and 4.4).

Lactation:
Because no information is available regarding the use of Pritor during breast-feeding, Pritor is not recommended and alternative treatments with better established safety profiles during breast-feeding are preferable, especially while nursing a newborn or preterm infant.

### 4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, when driving vehicles or operating machinery it should be taken into account that dizziness or drowsiness may occasionally occur when taking antihypertensive therapy.

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The overall incidence of adverse events reported with telmisartan (41.4 %) was usually comparable to placebo (43.9 %) in placebo controlled trials. The incidence of adverse events was not dose related and showed no correlation with gender, age or race of the patients.

The adverse drug reactions listed below have been accumulated from all clinical trials including 5788 hypertensive patients treated with telmisartan.

Adverse reactions have been ranked under headings of frequency using the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

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|---|---|
| Rare: | Upper respiratory tract infection including pharyngitis and sinusitis |
| Not known: | Urinary tract infection including cystitis |

Blood and the lymphatic system disorders

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|---|---|
| Rare: | Anaemia, thrombocytopenia |
| Not known: | Eosinophilia |

Immune system disorders

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| Not known: | Hypersensitivity, anaphylactic reaction |

Metabolism and nutrition disorders

| | |
|---|---|
| Uncommon: | Hyperkalaemia |

Psychiatric disorders

| | |
|---|---|
| Rare: | Anxiety, depression |

Nervous system disorders

| | |
|---|---|
| Uncommon: | Syncope, insomnia |

Eye disorders

| | |
|---|---|
| Rare: | Abnormal vision |

Ear and labyrinth disorders

| | |
|---|---|
| Uncommon: | Vertigo |

Cardiac disorders

| | |
|---|---|
| Rare: | Tachycardia |
| Not known: | Bradycardia |

Vascular disorders

| | |
|---|---|
| Uncommon: | Hypotension |
| Rare: | Orthostatic hypotension |

Respiratory, thoracic and mediastinal disorders

| | |
|---|---|
| Uncommon: | Dyspnoea |

Gastrointestinal disorders

| | |
|---|---|
| Uncommon: | Abdominal pain, diarrhoea, dry mouth, dyspepsia, flatulence |
| Rare: | Stomach upset, vomiting |

Hepato-biliary disorders

| | |
|---|---|
| Rare: | Hepatic function abnormal/liver disorder |

Skin and subcutaneous tissue disorders

| | |
|---|---|
| Uncommon: | Hyperhidrosis, pruritus |
| Rare: | Erythema, angioedema, urticaria |
| Not known: | Drug eruption, toxic skin eruption, rash, eczema |

Muscoloskeletal and connective tissue disorders

| | |
|---|---|
| Uncommon: | Myalgia |
| Rare: | Arthralgia, back pain (e.g. sciatica), muscle cramps, pain in limb, weakness |
| Not known: | Tendonitis |

Renal and urinary disorders

| | |
|---|---|
| Uncommon: | Renal impairment including acute renal failure |

General disorders and administration site conditions

| | |
|---|---|
| Uncommon: | Chest pain |
| Rare: | Influenza-like illness |
| Not known: | Drug ineffective |

Investigations

| | |
|---|---|
| Rare: | Blood uric acid increased, blood creatinine increased, hepatic enzyme increased, blood creatine phosphokinase increased |
| Not known: | Haemoglobin decreased |

### 4.9 Overdose

There is limited information available with regard to overdose in humans.

Symptoms: The most prominent manifestations of telmisartan overdose were hypotension and tachycardia; bradycardia, dizziness, increase in serum creatinine, and acute renal failure have also been reported.

Treatment: Telmisartan is not removed by haemodialysis. The patient should be closely monitored, and the treatment should be symptomatic and supportive. Management depends on the time since ingestion and the severity of the symptoms. Suggested measures include induction of emesis and / or gastric lavage. Activated charcoal may be useful in the treatment of overdosage. Serum electrolytes and creatinine should be monitored frequently. If hypotension occurs, the patient should be placed in a supine position, with salt and volume replacement given quickly.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Angiotensin II Antagonists, plain, ATC Code: C09CA07.

Mechanism of action:
Telmisartan is an orally active and specific angiotensin II receptor (type $AT_1$) antagonist. Telmisartan displaces angiotensin II with very high affinity from its binding site at the $AT_1$ receptor subtype, which is responsible for the known actions of angiotensin II. Telmisartan does not exhibit any partial agonist activity at the $AT_1$ receptor. Telmisartan selectively binds the $AT_1$ receptor. The binding is long-lasting. Telmisartan does not show affinity for other receptors, including $AT_2$ and other less characterised AT receptors. The functional role of these receptors is not known, nor is the effect of their possible overstimulation by angiotensin II, whose levels are increased by telmisartan. Plasma aldosterone levels are decreased by telmisartan. Telmisartan does not inhibit human plasma renin or block ion channels. Telmisartan does not inhibit angiotensin converting enzyme (kininase II), the enzyme which also degrades bradykinin. Therefore it is not expected to potentiate bradykinin-mediated adverse effects.

In human, an 80 mg dose of telmisartan almost completely inhibits the angiotensin II evoked blood pressure increase. The inhibitory effect is maintained over 24 hours and still measurable up to 48 hours.

Clinical efficacy and safety:
After the first dose of telmisartan, the antihypertensive activity gradually becomes evident within 3 hours. The maximum reduction in blood pressure is generally attained 4 to 8 weeks after the start of treatment and is sustained during long-term therapy.

The antihypertensive effect persists constantly over 24 hours after dosing and includes the last 4 hours before the next dose as shown by ambulatory blood pressure measurements. This is confirmed by trough to peak ratios consistently above 80 % seen after doses of 40 and 80 mg of telmisartan in placebo controlled clinical studies. There is an apparent trend to a dose relationship to a time to recovery of baseline systolic blood pressure (SBP). In this respect data concerning diastolic blood pressure (DBP) are inconsistent.

In patients with hypertension telmisartan reduces both systolic and diastolic blood pressure without affecting pulse rate. The contribution of the medicinal product's diuretic and natriuretic effect to its hypotensive activity has still to be defined. The antihypertensive efficacy of telmisartan is comparable to that of agents representative of other classes of antihypertensive medicinal products (demonstrated in clinical trials comparing telmisartan to amlodipine, atenolol, enalapril, hydrochlorothiazide, and lisinopril).

Upon abrupt cessation of treatment with telmisartan, blood pressure gradually returns to pre-treatment values over a period of several days without evidence of rebound hypertension.

The incidence of dry cough was significantly lower in patients treated with telmisartan than in those given angiotensin converting enzyme inhibitors in clinical trials directly comparing the two antihypertensive treatments.

Beneficial effects of telmisartan on mortality and cardiovascular morbidity are currently unknown.

## 5.2 Pharmacokinetic properties

Absorption:
Absorption of telmisartan is rapid although the amount absorbed varies. The mean absolute bioavailability for telmisartan is about 50 %. When telmisartan is taken with food, the reduction in the area under the plasma concentration-time curve ($AUC_{0-\infty}$) of telmisartan varies from approximately 6 % (40 mg dose) to approximately 19 % (160 mg dose). By 3 hours after administration, plasma concentrations are similar whether telmisartan is taken fasting or with food.

Linearity/non-linearity:
The small reduction in AUC is not expected to cause a reduction in the therapeutic efficacy. There is no linear relationship between doses and plasma levels. $C_{max}$ and to a lesser extent AUC increase disproportionately at doses above 40 mg.

Distribution:
Telmisartan is largely bound to plasma protein (>99.5 %), mainly albumin and alpha-1 acid glycoprotein. The mean steady state apparent volume of distribution ($V_{dss}$) is approximately 500 l.

Metabolism:
Telmisartan is metabolised by conjugation to the glucuronide of the parent compound. No pharmacological activity has been shown for the conjugate.

Elimination:
Telmisartan is characterised by biexponential decay pharmacokinetics with a terminal elimination half-life of >20 hours. The maximum plasma concentration ($C_{max}$) and, to a smaller extent, the area

under the plasma concentration-time curve (AUC), increase disproportionately with dose. There is no evidence of clinically relevant accumulation of telmisartan taken at the recommended dose. Plasma concentrations were higher in females than in males, without relevant influence on efficacy.

After oral (and intravenous) administration telmisartan is nearly exclusively excreted with the faeces, mainly as unchanged compound. Cumulative urinary excretion is <1 % of dose. Total plasma clearance ($Cl_{tot}$) is high (approximately 1,000 ml/min) compared with hepatic blood flow (about 1,500 ml/min).

*Special Populations*

Gender effects:
Differences in plasma concentrations were observed, with $C_{max}$ and AUC being approximately 3- and 2-fold higher, respectively, in females compared to males.

Elderly patients:
The pharmacokinetics of telmisartan do not differ between the elderly and those younger than 65 years.

Patients with renal impairment:
In patients with mild to moderate and severe renal impairment, doubling of plasma concentrations was observed. However, lower plasma concentrations were observed in patients with renal insufficiency undergoing dialysis. Telmisartan is highly bound to plasma protein in renal-insufficient patients and cannot be removed by dialysis. The elimination half-life is not changed in patients with renal impairment.

Patients with hepatic impairment:
Pharmacokinetic studies in patients with hepatic impairment showed an increase in absolute bioavailability up to nearly 100 %. The elimination half-life is not changed in patients with hepatic impairment.

### 5.3 Preclinical safety data

In preclinical safety studies, doses producing exposure comparable to that in the clinical therapeutic range caused reduced red cell parameters (erythrocytes, haemoglobin, haematocrit), changes in renal haemodynamics (increased blood urea nitrogen and creatinine), as well as increased serum potassium in normotensive animals. In dogs, renal tubular dilation and atrophy were observed. Gastric mucosal injury (erosion, ulcers or inflammation) also was noted in rats and dogs. These pharmacologically-mediated undesirable effects, known from preclinical studies with both angiotensin converting enzyme inhibitors and angiotensin II receptor antagonists, were prevented by oral saline supplementation.

In both species, increased plasma renin activity and hypertrophy/hyperplasia of the renal juxtaglomerular cells were observed. These changes, also a class effect of angiotensin converting enzyme inhibitors and other angiotensin II receptor antagonists, do not appear to have clinical significance.

There is no evidence of a teratogenic effect, but animal studies indicated some hazardous potential of telmisartan to the postnatal development of the offspring such as lower body weight, delayed eye opening, and higher mortality.

There was no evidence of mutagenicity and relevant clastogenic activity in *in vitro* studies and no evidence of carcinogenicity in rats and mice.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Povidone (K25)
Meglumine
Sodium hydroxide
Sorbitol (E420)
Magnesium stearate.

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

4 years

### 6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.
Store in the original package in order to protect from moisture.

### 6.5 Nature and contents of container

Aluminium/aluminium blisters (PA/PA/Al/PVC/Al). One blister contains 7 or 10 tablets.

Pack sizes: Blister with 14, 28, 30, 56, 90, 98 or 280 tablets or perforated unit dose blisters with 28 x 1 tablets.

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal

No special requirements.

## 7. MARKETING AUTHORISATION HOLDER

Bayer Schering Pharma AG
13342 Berlin
Germany

## 8. MARKETING AUTHORISATION NUMBERS

EU/1/98/089/006 (14 tablets)
EU/1/98/089/007 (28 tablets)
EU/1/98/089/022 (30 tablets)
EU/1/98/089/008 (56 tablets)
EU/1/98/089/018 (90 tablets)
EU/1/98/089/009 (98 tablets)
EU/1/98/089/010 (280 tablets)
EU/1/98/089/016 (28 x 1 tablets)

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 December 1998
Date of last renewal: 11 December 2008

## 10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency (EMEA) http://www.emea.europa.eu/.

# ANNEX II

## A. MANUFACTURING AUTHORISATION HOLDERS RESPONSIBLE FOR BATCH RELEASE

## B. CONDITIONS OF THE MARKETING AUTHORISATION

## A MANUFACTURING AUTHORISATION HOLDERS RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers responsible for batch release

Bayer Schering Pharma AG
51368 Leverkusen
Germany

SmithKline Beecham Pharmaceuticals
Manor Royal
Crawley, West Sussex
RH10 2QJ
United Kingdom

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

## B CONDITIONS OF THE MARKETING AUTHORISATION

- **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER**

Medicinal product subject to medical prescription.

- **CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**

Not applicable.

- **OTHER CONDITIONS**

PSURs
The MAH will continue to submit yearly PSURs, unless otherwise specified by the CHMP.

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Carton**

## 1. NAME OF THE MEDICINAL PRODUCT

Pritor 20 mg tablets
telmisartan

## 2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 20 mg telmisartan.

## 3. LIST OF EXCIPIENTS

Contains sorbitol (E420).
Read the package leaflet for further information.

## 4. PHARMACEUTICAL FORM AND CONTENTS

14 tablets
28 tablets
30 tablets
56 tablets
90 tablets
98 tablets

## 5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

## 6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

## 7. OTHER SPECIAL WARNING(S), IF NECESSARY

## 8. EXPIRY DATE

EXP

## 9. SPECIAL STORAGE CONDITIONS

This medicinal product does not require any special storage conditions.
Store in the original package in order to protect from moisture.

## 10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

## 11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bayer Schering Pharma AG
13342 Berlin
Germany

## 12. MARKETING AUTHORISATION NUMBER(S)

EU/1/98/089/011
EU/1/98/089/012
EU/1/98/089/020
EU/1/98/089/013
EU/1/98/089/019
EU/1/98/089/014

## 13. BATCH NUMBER

Lot: {number}

## 14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

## 15. INSTRUCTIONS ON USE

## 16. INFORMATION IN BRAILLE

Pritor 20 mg

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Blister of 7 tablets**

## 1. NAME OF THE MEDICINAL PRODUCT

Pritor 20 mg tablets
telmisartan

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

Bayer (Logo)

## 3. EXPIRY DATE

EXP

## 4. BATCH NUMBER

Lot

## 5. OTHER

MON
TUE
WED
THU
FRI
SAT
SUN

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Any non 7 count blister**

## 1. NAME OF THE MEDICINAL PRODUCT

Pritor 20 mg tablets
telmisartan

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

Bayer (Logo)

## 3. EXPIRY DATE

EXP

## 4. BATCH NUMBER

Lot

## 5. OTHER

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Carton**

## 1. NAME OF THE MEDICINAL PRODUCT

Pritor 40 mg tablets
telmisartan

## 2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 40 mg telmisartan.

## 3. LIST OF EXCIPIENTS

Contains sorbitol (E420).
Read the package leaflet for further information.

## 4. PHARMACEUTICAL FORM AND CONTENTS

14 tablets
28 tablets
30 tablets
56 tablets
90 tablets
98 tablets
280 tablets
28 x 1 tablets

## 5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

## 6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

## 7. OTHER SPECIAL WARNING(S), IF NECESSARY

## 8. EXPIRY DATE

EXP

## 9. SPECIAL STORAGE CONDITIONS

This medicinal product does not require any special storage conditions.
Store in the original package in order to protect from moisture.

## 10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

## 11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bayer Schering Pharma AG
13342 Berlin
Germany

## 12. MARKETING AUTHORISATION NUMBER(S)

EU/1/98/089/001
EU/1/98/089/002
EU/1/98/089/021
EU/1/98/089/003
EU/1/98/089/017
EU/1/98/089/004
EU/1/98/089/005
EU/1/98/089/015

## 13. BATCH NUMBER

Lot: {number}

## 14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

## 15. INSTRUCTIONS ON USE

## 16. INFORMATION IN BRAILLE

Pritor 40 mg

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Blister of 7 tablets**

## 1. NAME OF THE MEDICINAL PRODUCT

Pritor 40 mg tablets
telmisartan

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

Bayer (Logo)

## 3. EXPIRY DATE

EXP

## 4. BATCH NUMBER

Lot

## 5. OTHER

MON
TUE
WED
THU
FRI
SAT
SUN

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Unit dose blister (28 x 1 tablets pack) or any non 7 count blister**

## 1. NAME OF THE MEDICINAL PRODUCT

Pritor 40 mg tablets
telmisartan

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

Bayer (Logo)

## 3. EXPIRY DATE

EXP

## 4. BATCH NUMBER

Lot

## 5. OTHER

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Carton**

## 1. NAME OF THE MEDICINAL PRODUCT

Pritor 80 mg tablets
telmisartan

## 2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 80 mg telmisartan.

## 3. LIST OF EXCIPIENTS

Contains sorbitol (E420).
Read the package leaflet for further information.

## 4. PHARMACEUTICAL FORM AND CONTENTS

14 tablets
28 tablets
30 tablets
56 tablets
90 tablets
98 tablets
280 tablets
28 x 1 tablets

## 5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

## 6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

## 7. OTHER SPECIAL WARNING(S), IF NECESSARY

## 8. EXPIRY DATE

EXP

## 9. SPECIAL STORAGE CONDITIONS

This medicinal product does not require any special storage conditions.
Store in the original package in order to protect from moisture.

## 10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

## 11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bayer Schering Pharma AG
13342 Berlin
Germany

## 12. MARKETING AUTHORISATION NUMBER(S)

EU/1/98/089/006
EU/1/98/089/007
EU/1/98/089/022
EU/1/98/089/008
EU/1/98/089/018
EU/1/98/089/009
EU/1/98/089/010
EU/1/98/089/016

## 13. BATCH NUMBER

Lot: {number}

## 14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

## 15. INSTRUCTIONS ON USE

## 16. INFORMATION IN BRAILLE

Pritor 80 mg

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Blister of 7 tablets**

## 1. NAME OF THE MEDICINAL PRODUCT

Pritor 80 mg tablets
telmisartan

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

Bayer (Logo)

## 3. EXPIRY DATE

EXP

## 4. BATCH NUMBER

Lot

## 5. OTHER

MON
TUE
WED
THU
FRI
SAT
SUN

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Unit dose blister (28 x 1 tablets pack) or any non 7 count blister**

## 1. NAME OF THE MEDICINAL PRODUCT

Pritor 80 mg tablets
telmisartan

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

Bayer (Logo)

## 3. EXPIRY DATE

EXP

## 4. BATCH NUMBER

Lot

## 5. OTHER

# B. PACKAGE LEAFLET

**PACKAGE LEAFLET: INFORMATION FOR THE USER**
**Pritor 20 mg tablets**
Telmisartan

**Read all of this leaflet carefully before you start taking this medicine.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet**:


## 1. WHAT PRITOR IS AND WHAT IT IS USED FOR

Pritor belongs to a class of medicines known as angiotensin II receptor antagonists. Angiotensin II is a substance produced in your body which causes your blood vessels to narrow, thus increasing your blood pressure. Pritor blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

**Pritor is used to** treat essential hypertension (high blood pressure). 'Essential' means that the high blood pressure is not caused by any other condition.

High blood pressure, if not treated, can damage blood vessels in several organs, which could lead sometimes to heart attack, heart or kidney failure, stroke, or blindness. There are usually no symptoms of high blood pressure before damage occurs. Thus it is important to regularly measure blood pressure to verify if it is within the normal range.

## 2. BEFORE YOU TAKE PRITOR

**Do not take Pritor**

- if you are allergic (hypersensitive) to telmisartan or any other ingredients included in Pritor tablets (see section Further information for a list of other ingredients).
- if you are more than 3 months pregnant. (It is also better to avoid Pritor in early pregnancy – see pregnancy section.)
- if you have severe liver problems such as cholestasis or biliary obstruction (problems with drainage of the bile from the liver and gall bladder) or any other severe liver disease.

If any of the above applies to you, tell your doctor or pharmacist before taking Pritor.

**Take special care with Pritor**

Please tell your doctor if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Kidney disease or kidney transplant.

- Renal artery stenosis (narrowing of the blood vessels to one or both kidneys).
- Liver disease.
- Heart trouble.
- Raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals).
- Low blood pressure (hypotension), likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy ('water tablets'), low-salt diet, diarrhoea, or vomiting.
- Elevated potassium levels in your blood.
- Diabetes.

You must tell your doctor if you think you are (or might become) pregnant. Pritor is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

In case of surgery or anaesthesia, you should tell your doctor that you are taking Pritor.

The use of Pritor in children and adolescents up to the age of 18 years is not recommended.

As with all other angiotensin II receptor antagonists, Pritor may be less effective in lowering the blood pressure in black patients.

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Your doctor may need to change the dose of these other medications or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below taken at the same time with Pritor:

- Lithium containing medicines to treat some types of depression.
- Medicines that may increase blood potassium levels such as salt substitutes containing potassium, potassium-sparing diuretics (certain 'water tablets'), ACE inhibitors, angiotensin II receptor antagonists, NSAIDs (non steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen), heparin, immunosuppressives (e.g. cyclosporin or tacrolimus), and the antibiotic trimethoprim.
- Diuretics ('water tablets'), especially if taken in high doses together with Pritor, may lead to excessive loss of body water and low blood pressure (hypotension).

As with other blood pressure lowering medicines, the effect of Pritor may be reduced when you take NSAIDs (non steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids.

Pritor may increase the blood pressure lowering effect of other medicines used to treat high blood pressure.

**Taking Pritor with food and drink**

You can take Pritor with or without food.

**Pregnancy and breast-feeding**

Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Pritor before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Pritor. Pritor is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Pritor is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

**Driving and using machines**

No information is available on the effect of Pritor on the ability to drive or operate machinery. Some people feel dizzy or tired when they are treated for high blood pressure. If you feel dizzy or tired, do not drive or operate machinery.

**Important information about some of the ingredients of Pritor**

Pritor contains sorbitol.
If you are intolerant to some sugars, consult your doctor before taking Pritor.

## 3. HOW TO TAKE PRITOR

Always take Pritor exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose of Pritor is one tablet a day. Try to take the tablet at the same time each day.
You can take Pritor with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. It is important that you take Pritor every day until your doctor tells you otherwise. If you have the impression that the effect of Pritor is too strong or too weak, talk to your doctor or pharmacist.

The usual dose of Pritor for most patients is one 40 mg tablet once a day to control blood pressure over the 24-hour period. Your doctor has recommended a lower dose of one 20 mg tablet daily. Pritor may also be used in combination with diuretics ('water tablets') such as hydrochlorothiazide which has been shown to have an additive blood pressure lowering effect with Pritor.

If your liver is not working properly, the usual dose should not exceed 40 mg once daily.

**If you take more Pritor than you should**

If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately.

**If you forget to take Pritor**

If you forget to take a dose, do not worry. Take it as soon as you remember then carry on as before. If you do not take your tablet on one day, take your normal dose on the next day. ***Do not*** take a double dose to make up for forgotten individual doses.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Pritor can cause side effects, although not everybody gets them.
These side effects may occur with certain frequencies, which are defined as follows:

- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100

- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data.

Uncommon side effects may include:
High potassium levels, fainting (syncope), difficulty falling asleep, feeling of spinning (vertigo), low blood pressure (hypotension), shortness of breath, abdominal pain, diarrhoea, dry mouth, discomfort in the abdomen, bloating, increased sweating, itching, muscle pain (myalgia), kidney impairment including acute kidney failure, and pain in the chest.

Rare side effects may include:
upper respiratory tract infection (e.g. sore throat, inflamed sinuses, common cold), deficiency in red blood cells (anaemia), low platelet count (thrombocytopenia), feeling anxious, feeling sad (depression), impaired vision, fast heart beat (tachycardia), dizziness on standing up (orthostatic hypotension), upset stomach, vomiting, abnormal liver function, redness of skin, rapid swelling of the skin and mucosa (angioedema), hives (urticaria), joint pain (arthralgia), back pain, muscle cramps, pain in extremity, symptoms of weakness, flu-like-illness, increased levels of uric acid, creatinine, hepatic enzymes or creatine phosphokinase in the blood.

Side effects of unknown frequency may include:
urinary tract infections, increase in certain white blood cells (eosinophilia), allergic reaction (e.g. rash, itching, difficulty breathing, wheezing, swelling of the face or low blood pressure), slow heart rate (bradycardia), drug rash, eczema (a skin disorder), inflammation of the tendons, ineffectiveness of Pritor and decreased haemoglobin (a blood protein).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## 5. HOW TO STORE PRITOR

Keep out of the reach and sight of children.

Do not use Pritor after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions. You should store your medicine in the original package in order to protect the tablets from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### What Pritor contains

The active substance is telmisartan. Each tablet contains 20 mg telmisartan.
The other ingredients are povidone, meglumine, sodium hydroxide, sorbitol (E420) and magnesium stearate.

### What Pritor looks like and contents of the pack

Pritor 20 mg tablets are white, round and engraved with the code number '50H' on one side and the company logo on the other side.

Pritor is available in blister packs containing 14, 28, 30, 56, 90 or 98 tablets.

Not all pack sizes may be marketed in your country.

**Marketing Authorisation Holder**
Bayer Schering Pharma AG
51368 Leverkusen
Germany

**Manufacturer**
Bayer Schering Pharma AG
51368 Leverkusen
Germany

and

SmithKline Beecham Pharmaceuticals
Manor Royal
Crawley, West Sussex
RH10 2QJ
United Kingdom

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

| | |
|---|---|
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| **Danmark**<br>Bayer A/S<br>Tlf: +45-45 23 50 00 | **Nederland**<br>Bayer B.V., Bayer Schering Pharma<br>Tel: +31-(0)297-28 06 66 |
| **Deutschland**<br>Bayer Vital GmbH<br>Tel: +49-(0)214-30 513 48 | **Norge**<br>Bayer AS<br>Tlf. +47 24 11 18 00 |
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| **España**<br>Química Farmacéutica Bayer S.L.<br>Tel: +34-93-495 65 00 | **Portugal**<br>Bayer Portugal S.A<br>Tel: +351-21-416 42 00 |
| **France**<br>Bayer Santé<br>Tél: +33-3 20 20 80 80 | **România**<br>SC Bayer SRL<br>Tel.: +40 21 528 59 00 |
| **Ireland**<br>Bayer Limited<br>Tel: +353 1 299 93 13 | **Slovenija**<br>Bayer d. o. o.<br>Tel.: +386-1-58 14 400 |
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| **Lietuva**<br>UAB Bayer<br>Tel. +37 05 23 36 868 | |

**This leaflet was last approved in**

Detailed information on this medicine is available on the European Medicines Agency (EMEA) web site: http://www.emea.europa.eu/.

**PACKAGE LEAFLET: INFORMATION FOR THE USER**
**Pritor 40 mg tablets**
Telmisartan

**Read all of this leaflet carefully before you start taking this medicine.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet**:


## 1. WHAT PRITOR IS AND WHAT IT IS USED FOR

Pritor belongs to a group of medicines known as angiotensin II receptor antagonists. Angiotensin II is a substance produced in your body which causes your blood vessels to narrow, thus increasing your blood pressure. Pritor blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

**Pritor is used to** treat essential hypertension (high blood pressure). 'Essential' means that the high blood pressure is not caused by any other condition.

High blood pressure, if not treated, can damage blood vessels in several organs, which could lead sometimes to heart attack, heart or kidney failure, stroke, or blindness. There are usually no symptoms of high blood pressure before damage occurs. Thus it is important to regularly measure blood pressure to verify if it is within the normal range.

## 2. BEFORE YOU TAKE PRITOR

**Do not take Pritor**

- if you are allergic (hypersensitive) to telmisartan or any other ingredients included in Pritor tablets (see section Further information for a list of other ingredients).
- if you are more than 3 months pregnant. (It is also better to avoid Pritor in early pregnancy – see pregnancy section.)
- if you have severe liver problems such as cholestasis or biliary obstruction (problems with drainage of the bile from the liver and gall bladder) or any other severe liver disease.

If any of the above applies to you, tell your doctor or pharmacist before taking Pritor.

**Take special care with Pritor**

Please tell your doctor if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Kidney disease or kidney transplant.

- Renal artery stenosis (narrowing of the blood vessels to one or both kidneys).
- Liver disease.
- Heart trouble.
- Raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals).
- Low blood pressure (hypotension), likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy ('water tablets'), low-salt diet, diarrhoea, or vomiting.
- Elevated potassium levels in your blood.
- Diabetes.

You must tell your doctor if you think you are (or might become) pregnant. Pritor is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

In case of surgery or anaesthesia, you should tell your doctor that you are taking Pritor.

The use of Pritor in children and adolescents up to the age of 18 years is not recommended.

As with all other angiotensin II receptor antagonists, Pritor may be less effective in lowering the blood pressure in black patients.

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Your doctor may need to change the dose of these other medications or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below taken at the same time with Pritor:

- Lithium containing medicines to treat some types of depression.
- Medicines that may increase blood potassium levels such as salt substitutes containing potassium, potassium-sparing diuretics (certain 'water tablets'), ACE inhibitors, angiotensin II receptor antagonists, NSAIDs (non steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen), heparin, immunosuppressives (e.g. cyclosporin or tacrolimus), and the antibiotic trimethoprim.
- Diuretics ('water tablets'), especially if taken in high doses together with Pritor, may lead to excessive loss of body water and low blood pressure (hypotension).

As with other blood pressure lowering medicines, the effect of Pritor may be reduced when you take NSAIDs (non steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids.

Pritor may increase the blood pressure lowering effect of other medicines used to treat high blood pressure.

**Taking Pritor with food and drink**

You can take Pritor with or without food.

**Pregnancy and breast-feeding**

Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Pritor before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Pritor. Pritor is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Pritor is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

**Driving and using machines**

No information is available on the effect of Pritor on the ability to drive or operate machinery. Some people feel dizzy or tired when they are treated for high blood pressure. If you feel dizzy or tired, do not drive or operate machinery.

**Important information about some of the ingredients of Pritor**

Pritor contains sorbitol.
If you are intolerant to some sugars, consult your doctor before taking Pritor.

## 3. HOW TO TAKE PRITOR

Always take Pritor exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose of Pritor is one tablet a day. Try to take the tablet at the same time each day.
You can take Pritor with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. It is important that you take Pritor every day until your doctor tells you otherwise. If you have the impression that the effect of Pritor is too strong or too weak, talk to your doctor or pharmacist.

The usual dose of Pritor for most patients is one 40 mg tablet once a day to control blood pressure over the 24-hour period. However, sometimes your doctor may recommend a lower dose of 20 mg or a higher dose of 80 mg. Alternatively, Pritor may be used in combination with diuretics ('water tablets') such as hydrochlorothiazide which has been shown to have an additive blood pressure lowering effect with Pritor.

If your liver is not working properly, the usual dose should not exceed 40 mg once daily.

**If you take more Pritor than you should**

If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately.

**If you forget to take Pritor**

If you forget to take a dose, do not worry. Take it as soon as you remember then carry on as before. If you do not take your tablet on one day, take your normal dose on the next day. ***Do not*** take a double dose to make up for forgotten individual doses.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Pritor can cause side effects, although not everybody gets them.
These side effects may occur with certain frequencies, which are defined as follows:

- very common: affects more than 1 user in 10

- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data.

Uncommon side effects may include:
High potassium levels, fainting (syncope), difficulty falling asleep, feeling of spinning (vertigo), low blood pressure (hypotension), shortness of breath, abdominal pain, diarrhoea, dry mouth, discomfort in the abdomen, bloating, increased sweating, itching, muscle pain (myalgia), kidney impairment including acute kidney failure, and pain in the chest.

Rare side effects may include:
upper respiratory tract infection (e.g. sore throat, inflamed sinuses, common cold), deficiency in red blood cells (anaemia), low platelet count (thrombocytopenia), feeling anxious, feeling sad (depression), impaired vision, fast heart beat (tachycardia), dizziness on standing up (orthostatic hypotension), upset stomach, vomiting, abnormal liver function, redness of skin, rapid swelling of the skin and mucosa (angioedema), hives (urticaria), joint pain (arthralgia), back pain, muscle cramps, pain in extremity, symptoms of weakness, flu-like-illness, increased levels of uric acid, creatinine, hepatic enzymes or creatine phosphokinase in the blood.

Side effects of unknown frequency may include:
urinary tract infections, increase in certain white blood cells (eosinophilia), allergic reaction (e.g. rash, itching, difficulty breathing, wheezing, swelling of the face or low blood pressure), slow heart rate (bradycardia), drug rash, eczema (a skin disorder), inflammation of the tendons, ineffectiveness of Pritor and decreased haemoglobin (a blood protein).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## 5. HOW TO STORE PRITOR

Keep out of the reach and sight of children.

Do not use Pritor after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions. You should store your medicine in the original package in order to protect the tablets from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

**What Pritor contains**

The active substance is telmisartan. Each tablet contains 40 mg telmisartan.
The other ingredients are povidone, meglumine, sodium hydroxide, sorbitol (E420) and magnesium stearate.

**What Pritor looks like and contents of the pack**

Pritor 40 mg tablets are white, oblong-shaped and engraved with the code '51H' on one side.

Pritor is available in blister packs containing 14, 28, 30, 56, 90, 98 or 280 tablets, or unit dose blister packs containing 28 x 1 tablets.

Not all pack sizes may be marketed in your country.

**Marketing Authorisation Holder**
Bayer Schering Pharma AG
51368 Leverkusen
Germany

**Manufacturer**
Bayer Schering Pharma AG
51368 Leverkusen
Germany

and

SmithKline Beecham Pharmaceuticals
Manor Royal
Crawley, West Sussex
RH10 2QJ
United Kingdom

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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| **Lietuva**<br>UAB Bayer<br>Tel. +37 05 23 36 868 | |

**This leaflet was last approved in**

Detailed information on this medicine is available on the European Medicines Agency (EMEA) web site: http://www.emea.europa.eu/.

**PACKAGE LEAFLET: INFORMATION FOR THE USER**
**Pritor 80 mg tablets**
Telmisartan

**Read all of this leaflet carefully before you start taking this medicine.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet**:


## 1. WHAT PRITOR IS AND WHAT IT IS USED FOR

Pritor belongs to a group of medicines known as angiotensin II receptor antagonists. Angiotensin II is a substance produced in your body which causes your blood vessels to narrow, thus increasing your blood pressure. Pritor blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

**Pritor is used to** treat essential hypertension (high blood pressure). 'Essential' means that the high blood pressure is not caused by any other condition.

High blood pressure, if not treated, can damage blood vessels in several organs, which could lead sometimes to heart attack, heart or kidney failure, stroke, or blindness. There are usually no symptoms of high blood pressure before damage occurs. Thus it is important to regularly measure blood pressure to verify if it is within the normal range.

## 2. BEFORE YOU TAKE PRITOR

### Do not take Pritor

- if you are allergic (hypersensitive) to telmisartan or any other ingredients included in Pritor tablets (see section Further information for a list of other ingredients).
- if you are more than 3 months pregnant. (It is also better to avoid Pritor in early pregnancy – see pregnancy section.)
- if you have severe liver problems such as cholestasis or biliary obstruction (problems with drainage of the bile from the liver and gall bladder) or any other severe liver disease.

If any of the above applies to you, tell your doctor or pharmacist before taking Pritor.

### Take special care with Pritor

Please tell your doctor if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Kidney disease or kidney transplant.

- Renal artery stenosis (narrowing of the blood vessels to one or both kidneys).
- Liver disease.
- Heart trouble.
- Raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals).
- Low blood pressure (hypotension), likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy ('water tablets'), low-salt diet, diarrhoea, or vomiting.
- Elevated potassium levels in your blood.
- Diabetes.

You must tell your doctor if you think you are (or might become) pregnant. Pritor is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

In case of surgery or anaesthesia, you should tell your doctor that you are taking Pritor.

The use of Pritor in children and adolescents up to the age of 18 years is not recommended.

As with all other angiotensin antagonists, Pritor may be less effective in lowering the blood pressure in black patients.

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Your doctor may need to change the dose of these other medications or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below taken at the same time with Pritor:

- Lithium containing medicines to treat some types of depression.
- Medicines that may increase blood potassium levels such as salt substitutes containing potassium, potassium-sparing diuretics (certain 'water tablets'), ACE inhibitors, angiotensin II receptor antagonists, NSAIDs (non steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen), heparin, immunosuppressives (e.g. cyclosporin or tacrolimus), and the antibiotic trimethoprim.
- Diuretics ('water tablets'), especially if taken in high doses together with Pritor, may lead to excessive loss of body water and low blood pressure (hypotension).

As with other blood pressure lowering medicines, the effect of Pritor may be reduced when you take NSAIDs (non steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids.

Pritor may increase the blood pressure lowering effect of other medicines used to treat high blood pressure.

**Taking Pritor with food and drink**

You can take Pritor with or without food.

**Pregnancy and breast-feeding**

Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Pritor before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Pritor. Pritor is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Pritor is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

**Driving and using machines**

No information is available on the effect of Pritor on the ability to drive or operate machinery. Some people feel dizzy or tired when they are treated for high blood pressure. If you feel dizzy or tired, do not drive or operate machinery.

**Important information about some of the ingredients of Pritor**

Pritor contains sorbitol.
If you are intolerant to some sugars, consult your doctor before taking Pritor.

## 3. HOW TO TAKE PRITOR

Always take Pritor exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose of Pritor is one tablet a day. Try to take the tablet at the same time each day.
You can take Pritor with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. It is important that you take Pritor every day until your doctor tells you otherwise. If you have the impression that the effect of Pritor is too strong or too weak, talk to your doctor or pharmacist.

The usual dose of Pritor for most patients is one 40 mg tablet once a day to control blood pressure over the 24 hour period. However, sometimes your doctor may recommend a lower dose of 20 mg or a higher dose of 80 mg. Alternatively, Pritor may be used in combination with diuretics ('water tablets') such as hydrochlorothiazide which has been shown to have an additive blood pressure lowering effect with Pritor.

If your liver is not working properly, the usual dose should not exceed 40 mg once daily.

**If you take more Pritor than you should**

If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately.

**If you forget to take Pritor**

If you forget to take a dose, do not worry. Take it as soon as you remember then carry on as before. If you do not take your tablet on one day, take your normal dose on the next day. ***Do not*** take a double dose to make up for forgotten individual doses.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Pritor can cause side effects, although not everybody gets them.
These side effects may occur with certain frequencies, which are defined as follows:

- very common: affects more than 1 user in 10

- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data.

Uncommon side effects may include:
High potassium levels, fainting (syncope), difficulty falling asleep, feeling of spinning (vertigo), low blood pressure (hypotension), shortness of breath, abdominal pain, diarrhoea, dry mouth, discomfort in the abdomen, bloating, increased sweating, itching, muscle pain (myalgia), kidney impairment including acute kidney failure, and pain in the chest.

Rare side effects may include:
upper respiratory tract infection (e.g. sore throat, inflamed sinuses, common cold), deficiency in red blood cells (anaemia), low platelet count (thrombocytopenia), feeling anxious, feeling sad (depression), impaired vision, fast heart beat (tachycardia), dizziness on standing up (orthostatic hypotension), upset stomach, vomiting, abnormal liver function, redness of skin, rapid swelling of the skin and mucosa (angioedema), hives (urticaria), joint pain (arthralgia), back pain, muscle cramps, pain in extremity, symptoms of weakness, flu-like-illness, increased levels of uric acid, creatinine, hepatic enzymes or creatine phosphokinase in the blood.

Side effects of unknown frequency may include:
urinary tract infections, increase in certain white blood cells (eosinophilia), allergic reaction (e.g. rash, itching, difficulty breathing, wheezing, swelling of the face or low blood pressure), slow heart rate (bradycardia), drug rash, eczema (a skin disorder), inflammation of the tendons, ineffectiveness of Pritor and decreased haemoglobin (a blood protein).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## 5. HOW TO STORE PRITOR

Keep out of the reach and sight of children.

Do not use Pritor after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions. You should store your medicine in the original package in order to protect the tablets from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

**What Pritor contains**

The active substance is telmisartan. Each tablet contains 80 mg telmisartan.
The other ingredients are povidone, meglumine, sodium hydroxide, sorbitol (E420) and magnesium stearate.

**What Pritor looks like and contents of the pack**

Pritor 80 mg tablets are white, oblong-shaped and engraved with the code '52H' on one side.

Pritor is available in blister packs containing 14, 28, 30, 56, 90, 98 or 280 tablets, or unit dose blister packs containing 28 x 1 tablets.

Not all pack sizes may be marketed in your country.

**Marketing Authorisation Holder**
Bayer Schering Pharma AG
51368 Leverkusen
Germany

**Manufacturer**
Bayer Schering Pharma AG
51368 Leverkusen
Germany

and

SmithKline Beecham Pharmaceuticals
Manor Royal
Crawley, West Sussex
RH10 2QJ
United Kingdom

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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