ANNEX III

LABELLING AND PACKAGE LEAFLET

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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 further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

PritorPlus 40/12.5 mg tablets

- The active substances are 40 mg telmisartan and 12.5 mg hydrochlorothiazide
- The other ingredients are lactose monohydrate, magnesium stearate, maize starch, meglumine, microcrystalline cellulose, povidone (K 25), red ferric oxide (E172), sodium hydroxide, sodium starch glycollate (type A) and sorbitol

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Manufacturer

SmithKline Beecham
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1. WHAT PRITORPLUS IS AND WHAT IT IS USED FOR

Tablet

Red and white oval shaped two layer tablet engraved with the company logo and the code GXES1.

PritorPlus is provided in blisters containing 14, 28, 28 x 1, 56 or 98 tablets, although not all pack sizes may be marketed.

Your doctor measured your blood pressure and found it to be high for your age. High blood pressure, if not treated, can damage blood vessels in several organs such as the heart, the kidneys, the brain and the eyes. Sometimes this can lead to a heart attack, heart or kidney failure, a stroke, or blindness. As there are usually no symptoms of high blood pressure before damage occurs, it is necessary to measure blood pressure to tell whether it is normal or not.

High blood pressure can be treated and controlled with medicines such as PritorPlus. Your doctor may also have suggested that you adjust your lifestyle to help to lower your blood pressure (losing weight, avoiding smoking, reducing alcohol consumption and restricting the amount of salt in the diet). He may also have encouraged you to take regular, mild (not strenuous) exercise such as walking and swimming.

PritorPlus is used for the treatment of high blood pressure (hypertension), when the doctor thinks it is appropriate to use a combination of the two active substances, telmisartan and hydrochlorothiazide. This is often the case when treatment with one of these substances alone did not lower your blood pressure enough.

Telmisartan belongs to a group of medicines called angiotensin II receptor antagonists. Angiotensin-II is a substance produced in your body which causes your blood vessels to narrow. This makes it harder for the blood to pass through them and so the pressure of the blood in the vessels increases. Telmisartan blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lower.

Hydrochlorothiazide belongs to a group of medicines called thiazide diuretics. Hydrochlorothiazide causes your urine output to increase, which also lowers your blood pressure.

2. BEFORE YOU TAKE PRITORPLUS

Do not take PritorPlus
- if you are hypersensitive (allergic) to telmisartan or any other ingredients included in PritorPlus tablets or to sulfonamide-derived medicines
- if you are between three and nine months pregnant
- if you are breast-feeding
- if you have cholestasis or biliary obstruction (problems with drainage of the bile from the gall bladder)
- if you suffer with severe liver disease
- if you suffer with severe kidney disease

If any of the above apply to you, tell your doctor or pharmacist.

Take special care with PritorPlus
- if you suffer from kidney disease or you have had a kidney transplant
- if you suffer from a condition causing persistently high calcium or low potassium levels in your blood
- if you suffer from liver disease
- if you suffer from excessive vomiting or diarrhoea
- if you suffer from heart trouble
- when you are diabetic
- if you suffer from raised aldosterone levels
- if you suffer from lupus erythematosus (also called “lupus” or “SLE”)
- children and adolescents up to 18 years. Since safety and efficacy of PritorPlus have not been established. PritorPlus should not be used in children and adolescents.

You should also tell your doctor if:
- you are on a low salt diet

Signs such as excessive thirst, a dry mouth, general weakness, drowsiness, muscle pain or cramps, nausea and vomiting, or an abnormally fast heart rate sometimes indicate an excessive effect of the hydrochlorothiazide ingredient of PritorPlus. If you experience any of these you should tell your doctor.

If you are going to have surgery or receive an anaesthetic, you should make sure that the doctor knows you are taking PritorPlus.

Pregnancy
It is better not to use PritorPlus during the first three months of pregnancy, and so you must tell your doctor if you are trying to become pregnant, or if you do become pregnant while taking it.
PritorPlus should not be taken if you are between three and nine months pregnant.

Breast-feeding
PritorPlus should not be taken if you are breast-feeding.

Driving and using machines:
Although PritorPlus is unlikely to affect your ability to drive or use machines, some people feel dizzy or tired during the treatment of high blood pressure. If you experience this you should talk to your doctor before driving or operating machinery.

Important information about some of the ingredients of PritorPlus:
Because of the amount of sorbitol in PritorPlus, this medicine should not be used by people with a condition called "hereditary fructose intolerance".

Taking other medicines:
It is important that you tell your doctor about all the medicines you are taking, even those you have bought yourself without a prescription, including herbal remedies.

The telmisartan in PritorPlus does not interact with most medicines. If you are taking lithium or digoxin however, your doctor may want to measure the levels of these in your blood while you are taking PritorPlus.

The hydrochlorothiazide in PritorPlus may interact with other medicines. Your doctor may perform special tests (for example blood tests) if you are also taking potassium supplements, potassium-containing salt substitutes or potassium sparing medicines, other diuretics ("water tablets"), some laxatives, medicines for gout, vitamin D supplements, medicines to control the rhythm of your heart or for diabetes (tablets or insulin).

It is important for your doctor to know if you are taking other medicines to lower your blood pressure, steroids, medicines to treat cancer, painkillers or arthritis medicines.

HOW TO TAKE PRITORPLUS

PritorPlus is only for adults and should not be taken by children and adolescents up to 18 years.
Always take PritorPlus exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

PritorPlus may have been prescribed because your previous treatment did not lower your blood pressure enough. If this is the case, your doctor will tell you how to switch from that treatment to PritorPlus.

The usual dose of PritorPlus is one tablet a day. If your blood pressure remains too high, your doctor may need to change your medication.
You can take PritorPlus with or without food. The tablets should be swallowed with liquid. Try to take the tablet at the same time each day. It is important that you take PritorPlus every day until your doctor tells you otherwise.

In patients with liver function problems the usual dose should not exceed 40/12.5 mg once daily.

If you take more PritorPlus than you should:
If you accidentally take too many tablets you should tell your doctor or your pharmacist, or contact your nearest hospital emergency department for advice.

If you forget to take PritorPlus:
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.

POSSIBLE SIDE EFFECTS

Like all medicines, PritorPlus can have side effects.

The following side effects have been commonly reported: abdominal pain, anxiety, arthrosis, back pain, changes in the blood components (cholesterol and potassium levels), diarrhoea, dizziness, eczema, impotence, influenza-like symptoms, joint pain, muscle pain, pain, stomach upset, upper respiratory tract infections including sore throat, bronchitis, pharyngitis and sinusitis, urinary tract infection, vertigo.

The following less common effects have also been seen: allergy, changes in the blood components (sugar and uric acid levels), leg pains, skin disorder.

In patients taking telmisartan alone the following additional side effects have been reported: abnormal vision, chest pain, dry mouth, flatulence, increased sweating tendinitis like symptoms Additionally rare reports of skin reddening, itching, faintness, insomnia, depression, vomiting, low blood pressure, slow pulse, fast pulse, shortness of breath, weakness, and lack of efficacy have been received.

As with other angiotensin II antagonists isolated cases of angioedema (swelling of the face) and other related side effects have been reported.

Patients taking hydrochlorothiazide, the other ingredient in PritorPlus, have occasionally suffered more serious conditions affecting the blood, skin or kidneys. Although these side effects have not been seen in patients taking PritorPlus, the possibility exists that they may occur.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING PRITORPLUS

Keep out of the reach and sight of children.
Store in the original package in order to protect from moisture.
Do not use PritorPlus after the expiry date stated on the blister and the carton.

Occasionally, the outer layer of the blister pack has been observed to separate from the inner layer between the blister pockets. No action need be taken if this is observed.

6. FURTHER INFORMATION

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

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This leaflet was last approved on {date}

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- Keep this leaflet. You may need to read it again.
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- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

PritorPlus 80/12.5 mg tablets

- The active substances are 80 mg telmisartan and 12.5 mg hydrochlorothiazide
- The other ingredients are lactose monohydrate, magnesium stearate, maize starch, meglumine, microcrystalline cellulose, povidone (K 25), red ferric oxide (E172), sodium hydroxide, sodium starch glycollate (type A) and sorbitol

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1. WHAT PRITORPLUS IS AND WHAT IT IS USED FOR

Tablet

Red and white oval shaped two layer tablet engraved with the company logo and the code GXES2.

PritorPlus is provided in blisters containing 14, 28, 28 x 1, 56 or 98 tablets, although not all pack sizes may be marketed.

Your doctor measured your blood pressure and found it to be high for your age. High blood pressure, if not treated, can damage blood vessels in several organs such as the heart, the kidneys, the brain and the eyes. Sometimes this can lead to a heart attack, heart or kidney failure, a stroke, or blindness. As there are usually no symptoms of high blood pressure before damage occurs, it is necessary to measure blood pressure to tell whether it is normal or not.

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Telmisartan belongs to a group of medicines called angiotensin II receptor antagonists. Angiotensin-II is a substance produced in your body which causes your blood vessels to narrow. This makes it harder for the blood to pass through them and so the pressure of the blood in the vessels increases. Telmisartan blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lower.

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- if you are between three and nine months pregnant
- if you are breast-feeding
- if you have cholestasis or biliary obstruction (problems with drainage of the bile from the gall bladder)
- if you suffer with severe liver disease
- if you suffer with severe kidney disease

If any of the above apply to you, tell your doctor or pharmacist.

Take special care with PritorPlus
- if you suffer from kidney disease or you have had a kidney transplant
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The following side effects have been commonly reported: abdominal pain, anxiety, arthrosis, back pain, changes in the blood components (cholesterol and potassium levels), diarrhoea, dizziness, eczema, impotence, influenza-like symptoms, joint pain, muscle pain, pain, stomach upset, upper respiratory tract infections including sore throat, bronchitis, pharyngitis and sinusitis, urinary tract infection, vertigo.

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If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING PRITORPLUS

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Occasionally, the outer layer of the blister pack has been observed to separate from the inner layer between the blister pockets. No action need be taken if this is observed.

6. FURTHER INFORMATION

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