

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### **Read all of this leaflet carefully before you start using 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.

### **What's in this leaflet:**

1. What Bextra is and what it is used for
2. Before you use Bextra
3. How to use Bextra
4. Possible side-effects
5. Storing Bextra
6. Further information

### **Bextra 10 mg film-coated tablets**

#### **Valdecoxib**

The active substance in Bextra is valdecoxib.

Bextra film-coated tablets contain 10 mg valdecoxib.

The other ingredients are lactose monohydrate, microcrystalline cellulose, pregelatinised starch (maize), croscarmellose sodium, and magnesium stearate. The coating of the tablet contains titanium dioxide (E171), hypromellose (E464), macrogol, polysorbate (E433).

#### **Marketing Authorisation Holder:**

Pharmacia-Pfizer EEIG, Hillbottom Road, High Wycombe, Buckinghamshire HP12 4PX, United Kingdom

#### **Manufacturer:**

Pharmacia Limited, Whalton Road, Morpeth, Northumberland NE61 3YA, United Kingdom

Heinrich Mack Nachf. GmbH & Co., KG, Heinrich-Mack-Str. 35, D-89257, Illertissen, Germany

## **1. WHAT BEXTRA IS AND WHAT IT IS USED FOR**

### **What Bextra is:**

Your body makes substances called prostaglandins. Some prostaglandins cause pain and swelling, whilst others help protect the stomach lining. Bextra works by reducing the amount of prostaglandins which produce pain and swelling without reducing the protective prostaglandins in the stomach.

Bextra treats pain and inflammation. It belongs to a group of medicines called Coxibs that act by inhibiting cyclooxygenase-2 (COX-2).

Bextra 10 mg film-coated tablets are white, capsule-shaped and are marked with '10' on one side and '7815' on the other side.

Bextra film-coated tablets are available in the following pack sizes:

Blister packs of: 5, 10, 20, 30, 30x1, 50, 100 and 100x1 film-coated tablets  
Bottle: 300 and 500 film-coated tablets

Not all pack sizes may be marketed.

**Osteoarthritis and rheumatoid arthritis:** Bextra is used to relieve the pain and swelling caused by osteoarthritis and rheumatoid arthritis.

**Primary dysmenorrhoea (menstrual pain and cramping):** Bextra is used to treat menstrual pain and cramping.

## **2. BEFORE YOU USE BEXTRA**

### **Do not use Bextra:**

- if you are hypersensitive (allergic) to valdecoxib or any of the other ingredients of Bextra
- if you have had an allergic reaction to acetylsalicylic acid (aspirin) or to other NSAIDs (e.g. ibuprofen) or to COX-2 inhibitors. Reactions might include wheezing (bronchospasm), badly blocked nose, itchy skin, rash or swelling of the face, lips or tongue, other allergic reactions or nasal polyps after taking these medicines
- if you have had an allergic reaction to a group of medicines called “sulphonamides” (e.g. some antibiotics used to treat infections)
- if you have a gastric or intestinal ulcer or gastrointestinal bleeding
- if you have inflammation of the intestines (ulcerative colitis or Crohn’s disease)
- if you have serious heart failure
- if you have serious liver disease
- if you are more than 6 months pregnant
- if you are breastfeeding

### **Talk to your doctor first before using Bextra**

#### **Make sure your doctor knows before you start taking Bextra:**

- if you have had an ulcer, bleeding or perforation of the gastrointestinal tract.
- if your heart, liver or kidneys are not working well
- if your blood pressure is high or if you are about to have heart surgery and have had a stroke
- if you have fluid retention (oedema, such as swollen ankles and feet)
- if you are dehydrated, for instance due to sickness, diarrhoea or the use of diuretics
- if you use medicines to reduce blood clotting
- if you have an infection, as it may hide fever (which is a sign of infection) and make you think, mistakenly, that you are better or that the infection is not serious
- if you are trying to become pregnant
- if you are pregnant

#### **Using Bextra with food and drink:**

Bextra may be taken with or without food.

#### **Pregnancy and Breast-feeding**

Like other medicines including aspirin or other NSAID medicines, if you are pregnant or thinking of becoming pregnant, you must inform your doctor before using Bextra. Do not use Bextra if you are more than 6 months pregnant. If you are breast-feeding, you must not use Bextra, as it is not known whether valdecoxib passes into breast milk.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines:**

If you feel dizzy or tired after using Bextra, do not drive or use heavy machinery until you feel better again.

**Using other medicines:**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Medicines can sometimes affect the way that other medicines work. You may need to reduce the amounts of Bextra or other medicines. Your doctor will advise you. Tell your doctor if you are taking any of the following medicines:

- Fluconazole or ketoconazole (used to treat fungal infections)
- ACE inhibitors (for high-blood pressure and heart failure)
- Diuretics (water tablets used to treat fluid retention)
- Cyclosporin and tacrolimus (used for immune system suppression e.g. after transplants)
- Warfarin (used to prevent blood from clotting)
- Lithium (used to treat depression)
- Rifampicin (used to treat bacterial infections)
- Antiarrhythmics (for irregular heartbeat)
- Phenytoin or carbamazepine (for epilepsy)
- Theophylline (for asthma)
- Methotrexate (for rheumatoid arthritis and cancer)
- Neuroleptics (used to treat psychoses)
- Omeprazole (used to treat gastric ulcers and oesophageal reflux disease)

Bextra can be used in combination with low dose aspirin.

### 3. HOW TO USE BEXTRA

Always take Bextra exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of Bextra is too strong or too weak, talk to your doctor or pharmacist.

**Recommended dose**

Bextra is for adults only; it is not for use in children.

**For osteoarthritis and rheumatoid arthritis** the recommended dose is 10 mg taken once a day. The maximum dose is 20 mg once daily. Bextra should be taken each day for as long as your doctor prescribes. Bextra will not cure your condition, but it should help to control pain, swelling and stiffness.

**For treatment of menstrual pain** the recommended dose is 40 mg taken once a day as required. On the first day you may take an additional 40 mg dose if needed. Only take 80 mg in total on the first day of treatment and after that only 40 mg once daily.

**It is important that you take your tablets as your doctor has instructed.**

**Elderly patients:**

If you are over 65 years of age and especially if you weigh less than 50 kg, you may not eliminate valdecoxib as quickly from your body. Your doctor may start you at the lowest recommended dose.

**Liver problems:**

If you have liver problems your doctor may start with the lowest recommended dose of Bextra for osteoarthritis and rheumatoid arthritis (10 mg once a day) and the dosage should not exceed 20 mg for primary dysmenorrhoea.

**Other medicines:**

Your doctor may prescribe a lower dose of Bextra if you are taking medicines called fluconazole or ketoconazole (see section "Using other medicines").

**If you take more Bextra than you should:**

Immediately contact your doctor, pharmacist or hospital.

**If you forget to take Bextra:**

If you forget to take a tablet, take it as soon as you remember. If it is almost time for your next tablet, do not take the tablet that you have missed. Thereafter, continue to use Bextra as your doctor had prescribed. Do not take a double dose to make up for forgotten individual doses.

**Effects when treatment with Bextra is stopped:**

Unless your doctor tells you to stop your treatment, it is important to keep taking Bextra as your doctor has prescribed.

#### 4. POSSIBLE SIDE-EFFECTS

Like all medicines, Bextra can have side-effects for some people. If you are worried about side-effects, talk to your doctor as some of these effects may be serious enough to require immediate medical attention.

**Stop taking Bextra and tell your doctor immediately:**

- if you have an allergic reaction such as skin rash, swelling of the face, lips or tongue which may cause difficulty breathing, or wheezing
- if you have blistering or peeling of the skin
- if you have jaundice (your skin or the whites of your eyes appear yellow)
- if you have any signs of bleeding in the stomach or intestine, such as passing a black or blood-stained bowel movement or vomiting blood

**More common side-effects which may affect more than 1 person in 100 are listed below:**

- Stomach ache, indigestion, diarrhoea, nausea, bloating and wind
- Itchy skin or rash
- Ankles, legs and feet may swell (fluid build-up)
- Raised blood pressure
- Dry mouth
- Dry socket after a tooth extraction
- Coughing
- Swollen sinuses, sore throat
- Anaemia
- Sleepiness or problems sleeping
- Urinary infections

**Less common side-effects which may affect up to 1 person in 100 are listed below:**

- Worsening of high blood pressure, dizziness
- General fluid build up in the body, swelling of/or around the eyes, aggravated allergy
- Surgical wounds may become infected

- Increased muscle tension, numbness
- Swelling of the mouth or stomach lining, heartburn
- Palpitation (awareness of your heart beat)
- Abnormalities in liver or kidney function tests
- Weight gain
- Bruising
- Nervousness, anxiety, confusion
- Hives
- Changes in the way things taste
- Blurred vision
- Wheezing
- Upper-respiratory tract infections
- Ulcers or bleeding
- Heart failure

**Rare side-effects which may affect up to 1 person in 1000 are listed below:**

- Allergic reactions such as skin rash, swelling of the face, lips and tongue, wheezing, difficulty breathing or swallowing
- Swelling, blistering or peeling of the skin
- Hoarse voice
- Obstruction of the digestive system
- Decrease in white blood cell and platelet counts
- Depression
- Sensitivity to light
- Inflammation of the kidney
- Stroke

If you are concerned about side-effects or notice any effects not mentioned in this leaflet, tell your doctor or pharmacist.

## **5. STORING BEXTRA**

Keep out of the reach and sight of children.

There are no special precautions for storage.

Do not use Bextra film-coated tablets after the expiry date stated on the box, blister strip or bottle.

## 6. FURTHER INFORMATION

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

### **Belgique / België /Belgien**

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**This leaflet was last approved on {date}**

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### **Bextra 20 mg film-coated tablets**

#### **Valdecoxib**

The active substance in Bextra is valdecoxib.

Bextra film-coated tablets contain 20 mg valdecoxib.

The other ingredients are lactose monohydrate, microcrystalline cellulose, pregelatinised starch (maize), croscarmellose sodium, and magnesium stearate. The coating of the tablet contains titanium dioxide (E171), hypromellose (E464), macrogol, polysorbate (E433).

#### **Marketing Authorisation Holder:**

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#### **Manufacturer:**

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Heinrich Mack Nachf. GmbH & Co., KG, Heinrich-Mack-Str. 35, D-89257, Illertissen, Germany

## **1. WHAT BEXTRA IS AND WHAT IT IS USED FOR**

### **What Bextra is:**

Your body makes substances called prostaglandins. Some prostaglandins cause pain and swelling, whilst others help protect the stomach lining. Bextra works by reducing the amount of prostaglandins which produce pain and swelling without reducing the protective prostaglandins in the stomach.

Bextra treats pain and inflammation. It belongs to a group of medicines called Coxibs that act by inhibiting cyclooxygenase-2 (COX-2).

Bextra 20 mg film-coated tablets are white, capsule-shaped and are marked with '20' on one side and '7815' on the other side.

Bextra film-coated tablets are available in the following pack sizes:

Blister packs of: 5, 10, 20, 30, 30x1, 50, 100 and 100x1 film-coated tablets  
Bottle: 300 and 500 film-coated tablets

Not all pack sizes may be marketed.

**Osteoarthritis and rheumatoid arthritis:** Bextra is used to relieve the pain and swelling caused by osteoarthritis and rheumatoid arthritis.

**Primary dysmenorrhoea (menstrual pain and cramping):** Bextra is used to treat menstrual pain and cramping.

## **2. BEFORE YOU USE BEXTRA**

### **Do not use Bextra:**

- if you are hypersensitive (allergic) to valdecoxib or any of the other ingredients of Bextra
- if you have had an allergic reaction to acetylsalicylic acid (aspirin) or to other NSAIDs (e.g. ibuprofen) or to COX-2 inhibitors. Reactions might include wheezing (bronchospasm), badly blocked nose, itchy skin, rash or swelling of the face, lips or tongue, other allergic reactions or nasal polyps after taking these medicines
- if you have had an allergic reaction to a group of medicines called “sulphonamides” (e.g. some antibiotics used to treat infections)
- if you have a gastric or intestinal ulcer or gastrointestinal bleeding
- if you have inflammation of the intestines (ulcerative colitis or Crohn’s disease)
- if you have serious heart failure
- if you have serious liver disease
- if you are more than 6 months pregnant
- if you are breastfeeding

### **Talk to your doctor first before using Bextra**

#### **Make sure your doctor knows** before you start taking Bextra:

- if you have had an ulcer, bleeding or perforation of the gastrointestinal tract.
- if your heart, liver or kidneys are not working well
- if your blood pressure is high or if you are about to have heart surgery and have had a stroke
- if you have fluid retention (oedema, such as swollen ankles and feet)
- if you are dehydrated, for instance due to sickness, diarrhoea or the use of diuretics
- if you use medicines to reduce blood clotting
- if you have an infection, as it may hide fever (which is a sign of infection) and make you think, mistakenly, that you are better or that the infection is not serious
- if you are trying to become pregnant
- if you are pregnant

#### **Using Bextra with food and drink:**

Bextra may be taken with or without food.

#### **Pregnancy and Breast-feeding**

Like other medicines including aspirin or other NSAID medicines, if you are pregnant or thinking of becoming pregnant, you must inform your doctor before using Bextra. Do not use Bextra if you are more than 6 months pregnant. If you are breast-feeding, you must not use Bextra, as it is not known whether valdecoxib passes into breast milk.

Ask your doctor or pharmacist for advice before taking any medicine.

#### **Driving and using machines:**

If you feel dizzy or tired after using Bextra, do not drive or use heavy machinery until you feel better again.

**Using other medicines:**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Medicines can sometimes affect the way that other medicines work. You may need to reduce the amounts of Bextra or other medicines. Your doctor will advise you. Tell your doctor if you are taking any of the following medicines:

- Fluconazole or ketoconazole (used to treat fungal infections)
- ACE inhibitors (for high-blood pressure and heart failure)
- Diuretics (water tablets used to treat fluid retention)
- Cyclosporin and tacrolimus (used for immune system suppression e.g. after transplants)
- Warfarin (used to prevent blood from clotting)
- Lithium (used to treat depression)
- Rifampicin (used to treat bacterial infections)
- Antiarrhythmics (for irregular heartbeat)
- Phenytoin or carbamazepine (for epilepsy)
- Theophylline (for asthma)
- Methotrexate (for rheumatoid arthritis and cancer)
- Neuroleptics (used to treat psychoses)
- Omeprazole (used to treat gastric ulcers and oesophageal reflux disease)

Bextra can be used in combination with low dose aspirin.

### **3. HOW TO USE BEXTRA**

Always take Bextra exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of Bextra is too strong or too weak, talk to your doctor or pharmacist.

**Recommended dose**

Bextra is for adults only; it is not for use in children.

**For osteoarthritis and rheumatoid arthritis** the recommended dose is 10 mg taken once a day. The maximum dose is 20 mg once daily. Bextra should be taken each day for as long as your doctor prescribes. Bextra will not cure your condition, but it should help to control pain, swelling and stiffness.

**For treatment of menstrual pain** the recommended dose is 40 mg taken once a day as required. On the first day you may take an additional 40 mg dose if needed. Only take 80 mg in total on the first day of treatment and after that only 40 mg once daily.

**It is important that you take your tablets as your doctor has instructed.**

**Elderly patients:**

If you are over 65 years of age and especially if you weigh less than 50 kg, you may not eliminate valdecoxib as quickly from your body. Your doctor may start you at the lowest recommended dose.

**Liver problems:**

If you have liver problems your doctor may start with the lowest recommended dose of Bextra for osteoarthritis and rheumatoid arthritis (10 mg once a day) and the dosage should not exceed 20 mg for primary dysmenorrhoea.

**Other medicines:**

Your doctor may prescribe a lower dose of Bextra if you are taking medicines called fluconazole or ketoconazole (see section "Using other medicines").

**If you take more Bextra than you should:**

Immediately contact your doctor, pharmacist or hospital.

**If you forget to take Bextra:**

If you forget to take a tablet, take it as soon as you remember. If it is almost time for your next tablet, do not take the tablet that you have missed. Thereafter, continue to use Bextra as your doctor had prescribed. Do not take a double dose to make up for forgotten individual doses.

**Effects when treatment with Bextra is stopped:**

Unless your doctor tells you to stop your treatment, it is important to keep taking Bextra as your doctor has prescribed.

#### 4. POSSIBLE SIDE-EFFECTS

Like all medicines, Bextra can have side-effects for some people. If you are worried about side-effects, talk to your doctor as some of these effects may be serious enough to require immediate medical attention.

**Stop taking Bextra and tell your doctor immediately:**

- if you have an allergic reaction such as skin rash, swelling of the face, lips or tongue which may cause difficulty breathing, or wheezing
- if you have blistering or peeling of the skin
- if you have jaundice (your skin or the whites of your eyes appear yellow)
- if you have any signs of bleeding in the stomach or intestine, such as passing a black or blood-stained bowel movement or vomiting blood

**More common side-effects which may affect more than 1 person in 100 are listed below:**

- Stomach ache, indigestion, diarrhoea, nausea, bloating and wind
- Itchy skin or rash
- Ankles, legs and feet may swell (fluid build-up)
- Raised blood pressure
- Dry mouth
- Dry socket after a tooth extraction
- Coughing
- Swollen sinuses, sore throat
- Anaemia
- Sleepiness or problems sleeping
- Urinary infections

**Less common side-effects which may affect up to 1 person in 100 are listed below:**

- Worsening of high blood pressure, dizziness
- General fluid build up in the body, swelling of/or around the eyes, aggravated allergy
- Surgical wounds may become infected
- Increased muscle tension, numbness

- Swelling of the mouth or stomach lining, heartburn
- Palpitation (awareness of your heart beat)
- Abnormalities in liver or kidney function tests
- Weight gain
- Bruising
- Nervousness, anxiety, confusion
- Hives
- Changes in the way things taste
- Blurred vision
- Wheezing
- Upper-respiratory tract infections
- Ulcers or bleeding
- Heart failure

**Rare side-effects which may affect up to 1 person in 1000 are listed below:**

- Allergic reactions such as skin rash, swelling of the face, lips and tongue, wheezing, difficulty breathing or swallowing
- Swelling, blistering or peeling of the skin
- Hoarse voice
- Obstruction of the digestive system
- Decrease in white blood cell and platelet counts
- Depression
- Sensitivity to light
- Inflammation of the kidney
- Stroke

If you are concerned about side-effects or notice any effects not mentioned in this leaflet, tell your doctor or pharmacist.

## **5. STORING BEXTRA**

Keep out of the reach and sight of children.

There are no special precautions for storage.

Do not use Bextra film-coated tablets after the expiry date stated on the box, blister strip or bottle.

## 6. FURTHER INFORMATION

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

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### **Bextra 40 mg film-coated tablets**

#### **Valdecoxib**

The active substance in Bextra is valdecoxib.

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Bextra film-coated tablets are available in the following pack sizes:

Blister packs of:           2 and 5 film-coated tablets  
Bottle:                    300 and 500 film-coated tablets



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**Osteoarthritis and rheumatoid arthritis:** Bextra is used to relieve the pain and swelling caused by osteoarthritis and rheumatoid arthritis.

**Primary dysmenorrhoea (menstrual pain and cramping):** Bextra is used to treat menstrual pain and cramping.

## **2. BEFORE YOU USE BEXTRA**

### **Do not use Bextra:**

- if you are hypersensitive (allergic) to valdecoxib or any of the other ingredients of Bextra
- if you have had an allergic reaction to acetylsalicylic acid (aspirin) or to other NSAIDs (e.g. ibuprofen) or to COX-2 inhibitors. Reactions might include wheezing (bronchospasm), badly blocked nose, itchy skin, rash or swelling of the face, lips or tongue, other allergic reactions or nasal polyps after taking these medicines
- if you have had an allergic reaction to a group of medicines called “sulphonamides” (e.g. some antibiotics used to treat infections)
- if you have a gastric or intestinal ulcer or gastrointestinal bleeding
- if you have inflammation of the intestines (ulcerative colitis or Crohn’s disease)
- if you have serious heart failure
- if you have serious liver disease
- if you are more than 6 months pregnant
- if you are breastfeeding

### **Talk to your doctor first before using Bextra**

#### **Make sure your doctor knows before you start taking Bextra:**

- if you have had an ulcer, bleeding or perforation of the gastrointestinal tract.
- if your heart, liver or kidneys are not working well
- if your blood pressure is high or if you are about to have heart surgery and have had a stroke
- if you have fluid retention (oedema, such as swollen ankles and feet)
- if you are dehydrated, for instance due to sickness, diarrhoea or the use of diuretics
- if you use medicines to reduce blood clotting
- if you have an infection, as it may hide fever (which is a sign of infection) and make you think, mistakenly, that you are better or that the infection is not serious
- if you are trying to become pregnant
- if you are pregnant

#### **Using Bextra with food and drink:**

Bextra may be taken with or without food.

#### **Pregnancy and Breast-feeding**

Like other medicines including aspirin or other NSAID medicines, if you are pregnant or thinking of becoming pregnant, you must inform your doctor before using Bextra. Do not use Bextra if you are more than 6 months pregnant. If you are breast-feeding, you must not use Bextra, as it is not known whether valdecoxib passes into breast milk.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines:**

If you feel dizzy or tired after using Bextra, do not drive or use heavy machinery until you feel better again.

**Using other medicines:**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Medicines can sometimes affect the way that other medicines work. You may need to reduce the amounts of Bextra or other medicines. Your doctor will advise you. Tell your doctor if you are taking any of the following medicines:

- Fluconazole or ketoconazole (used to treat fungal infections)
- ACE inhibitors (for high-blood pressure and heart failure)
- Diuretics (water tablets used to treat fluid retention)
- Cyclosporin and tacrolimus (used for immune system suppression e.g. after transplants)
- Warfarin (used to prevent blood from clotting)
- Lithium (used to treat depression)
- Rifampicin (used to treat bacterial infections)
- Antiarrhythmics (for irregular heartbeat)
- Phenytoin or carbamazepine (for epilepsy)
- Theophylline (for asthma)
- Methotrexate (for rheumatoid arthritis and cancer)
- Neuroleptics (used to treat psychoses)
- Omeprazole (used to treat gastric ulcers and oesophageal reflux disease)

Bextra can be used in combination with low dose aspirin.

### 3. HOW TO USE BEXTRA

Always take Bextra exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of Bextra is too strong or too weak, talk to your doctor or pharmacist.

**Recommended dose**

Bextra is for adults only; it is not for use in children.

**For osteoarthritis and rheumatoid arthritis** the recommended dose is 10 mg taken once a day. The maximum dose is 20 mg once daily. Bextra should be taken each day for as long as your doctor prescribes. Bextra will not cure your condition, but it should help to control pain, swelling and stiffness.

**For treatment of menstrual pain** the recommended dose is 40 mg taken once a day as required. On the first day you may take an additional 40 mg dose if needed. Only take 80 mg in total on the first day of treatment and after that only 40 mg once daily.

**It is important that you take your tablets as your doctor has instructed.**

**Elderly patients:**

If you are over 65 years of age and especially if you weigh less than 50 kg, you may not eliminate valdecoxib as quickly from your body. Your doctor may start you at the lowest recommended dose.

**Liver problems:**

If you have liver problems your doctor may start with the lowest recommended dose of Bextra for osteoarthritis and rheumatoid arthritis (10 mg once a day) and the dosage should not exceed 20 mg for primary dysmenorrhoea.

**Other medicines:**

Your doctor may prescribe a lower dose of Bextra if you are taking medicines called fluconazole or ketoconazole (see section "Using other medicines").

**If you take more Bextra than you should:**

Immediately contact your doctor, pharmacist or hospital.

**If you forget to take Bextra:**

If you forget to take a tablet, take it as soon as you remember. If it is almost time for your next tablet, do not take the tablet that you have missed. Thereafter, continue to use Bextra as your doctor had prescribed. Do not take a double dose to make up for forgotten individual doses.

**Effects when treatment with Bextra is stopped:**

Unless your doctor tells you to stop your treatment, it is important to keep taking Bextra as your doctor has prescribed.

#### 4. POSSIBLE SIDE-EFFECTS

Like all medicines, Bextra can have side-effects for some people. If you are worried about side-effects, talk to your doctor as some of these effects may be serious enough to require immediate medical attention.

**Stop taking Bextra and tell your doctor immediately:**

- if you have an allergic reaction such as skin rash, swelling of the face, lips or tongue which may cause difficulty breathing, or wheezing
- if you have blistering or peeling of the skin
- if you have jaundice (your skin or the whites of your eyes appear yellow)
- if you have any signs of bleeding in the stomach or intestine, such as passing a black or blood-stained bowel movement or vomiting blood

**More common side-effects which may affect more than 1 person in 100 are listed below:**

- Stomach ache, indigestion, diarrhoea, nausea, bloating and wind
- Itchy skin or rash
- Ankles, legs and feet may swell (fluid build-up)
- Raised blood pressure
- Dry mouth
- Dry socket after a tooth extraction
- Coughing
- Swollen sinuses, sore throat
- Anaemia
- Sleepiness or problems sleeping
- Urinary infections

**Less common side-effects which may affect up to 1 person in 100 are listed below:**

- Worsening of high blood pressure, dizziness
- General fluid build up in the body, swelling of/or around the eyes, aggravated allergy
- Surgical wounds may become infected

- Increased muscle tension, numbness
- Swelling of the mouth or stomach lining, heartburn
- Palpitation (awareness of your heart beat)
- Abnormalities in liver or kidney function tests
- Weight gain
- Bruising
- Nervousness, anxiety, confusion
- Hives
- Changes in the way things taste
- Blurred vision
- Wheezing
- Upper-respiratory tract infections
- Ulcers or bleeding
- Heart failure

**Rare side-effects which may affect up to 1 person in 1000 are listed below:**

- Allergic reactions such as skin rash, swelling of the face, lips and tongue, wheezing, difficulty breathing or swallowing
- Swelling, blistering or peeling of the skin
- Hoarse voice
- Obstruction of the digestive system
- Decrease in white blood cell and platelet counts
- Depression
- Sensitivity to light
- Inflammation of the kidney
- Stroke

If you are concerned about side-effects or notice any effects not mentioned in this leaflet, tell your doctor or pharmacist.

## **5. STORING BEXTRA**

Keep out of the reach and sight of children.

There are no special precautions for storage.

Do not use Bextra film-coated tablets after the expiry date stated on the box, blister strip or bottle.

## 6. FURTHER INFORMATION

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

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