

## PACKAGE LEAFLET: INFORMATION FOR THE USER

**Arcoxia**  
**60 mg Film coated Tablets**  
(etoricoxib)

**Arcoxia**  
**90 mg Film coated Tablets**  
(etoricoxib)

**Arcoxia**  
**120 mg Film coated Tablets**  
(etoricoxib)

**Read all of the leaflet carefully before you start taking this medicine.** - Keep this leaflet. You may want 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:**

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

Arcoxia is a non-steroidal anti-inflammatory drug (NSAID). It is a member of a class of NSAIDs known as cyclo-oxygenase-2 (COX-2) selective inhibitors. Cyclo-oxygenase is an enzyme responsible for the generation of prostaglandins, which are naturally occurring chemicals in the body that can cause pain and inflammation. The production of prostaglandins by the enzyme COX-2 is increased in certain diseases such as arthritis. By blocking COX-2, Arcoxia reduces the amount of prostaglandins produced and reduces pain and inflammation. Arcoxia is not a narcotic.

Your doctor has prescribed these tablets to relieve the symptoms of your osteoarthritis, rheumatoid arthritis or gout.

### **What is osteoarthritis?**

Osteoarthritis is a disease of the joints, resulting from the gradual breakdown of the cartilage that cushions the ends of the bones, resulting in inflammation, pain, tenderness, stiffness and physical disability.

### **What is rheumatoid arthritis?**

Rheumatoid arthritis is a chronic disease of the joints. It causes pain, stiffness, swelling, and progressive loss of function in the joints affected and inflammation in other body organs.

### **What is gout?**

Gout is a disorder characterized by sudden, recurring attacks of very painful arthritis, which may lead to swelling and inflammation. It is caused by deposits of mineral crystals in the joint.

## **2. BEFORE YOU TAKE ARCOXIA**

### **Do not take Arcoxia:**

- if you are allergic (hypersensitive) to etoricoxib or any of the ingredients of etoricoxib
- if you have an active stomach ulcer or bleeding in the stomach or intestines
- if you have serious liver disease
- if you have serious kidney disease
- if you have previously experienced any of the following after taking aspirin (acetylsalicylic acid) or other anti-inflammatory medications, including COX-2 inhibitors: asthma (wheezing or inability to breathe easily), nasal irritation, nasal polyps, or allergic symptoms such as swelling of the face, lips, tongue or throat and/or itching skin rash
- if you are or could be pregnant or are breast-feeding (see ‘Pregnancy and breast-feeding’)
- if you are under 16 years of age
- if you have inflammatory bowel disease
- if your doctor has diagnosed heart problems including heart failure (moderate or severe types), angina (chest pain) or if you have had a heart attack, bypass surgery, peripheral arterial disease (poor circulation in legs or feet due to narrow or blocked arteries), or any kind of stroke (including mini-stroke, transient ischaemic attack or TIA). Etoricoxib may slightly increase your risk of heart attack and stroke and this is why it should not be used in those who have already had heart problems or stroke
- if you have high blood pressure that has not been controlled by treatment (check with your doctor or nurse if you are not sure whether your blood pressure is adequately controlled)

If you think any of these are relevant to you, do not take the tablets until you have consulted your doctor.

### **Take special care with ARCOXIA**

If you answer ‘yes’ to any of the following questions and you have not already discussed these with your doctor, go back to your doctor and ask for advice. Arcoxia may not be suitable for you, or you may need to be monitored regularly while taking it:

- Do you have a history of stomach bleeding or ulcers?
- Are you dehydrated, for example by a prolonged bout of vomiting or diarrhoea?
- Do you have swelling due to fluid retention?
- Do you have a history of heart failure, heart attack or any other form of heart disease?
- Do you have a history of stroke or mini stroke?
- Do you have a history of raised blood pressure?
- Do you have any history of liver or kidney disease?
- Are you being treated for an infection? Arcoxia can mask or hide a fever, which is a sign of infection.
- Are you a woman trying to become pregnant?
- Do you have any conditions such as high blood pressure, diabetes, high cholesterol or are you a smoker? These can increase your risk of heart disease and you need to discuss with your doctor if this medicine is suitable for you.
- Do you have a history of allergy to other drugs? Some selective COX-2 inhibitors have been associated with an increased risk of skin reactions in patients with a history of any drug allergy.

### **The following are things to be aware of while taking Arcoxia:**

- If you are elderly (i.e., over 65 years of age) or have kidney, liver or heart disease, your doctor will

want to keep a regular check on you.

- If you develop any symptoms that could indicate liver problems, such as yellowing of the skin and eyes, it is important that you see your doctor as soon as possible.
- If you develop severe or persistent abdominal pain and/or your stools become black, you must consult a doctor on an urgent basis.
- If any of the following symptoms: **shortness of breath, chest pains or ankle swelling** appear or start to get worse, stop your treatment with Arcoxia and consult a doctor.
- If you develop any symptoms that could indicate a severe allergic reaction such as inability to breathe or skin reactions such as ulcers or blistering, you must consult a doctor on an urgent basis.
- Your doctor will want to discuss your treatment from time to time. It is important that you use the lowest dose that controls your pain and you should not take Arcoxia for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses. - Arcoxia can increase blood pressure in some people, especially in high doses, and this could increase the risk of heart attacks and strokes. Your doctor will want to check your blood pressure from time to time, to make sure that it is safe to continue treatment.

### **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.

In particular if you are taking any of the following medicines, your doctor may want to monitor you to check that your medicines are working properly, once you start taking Arcoxia:

- anti-clotting agents, such as warfarin or other oral anticoagulants
- rifampicin (an antibiotic)
- methotrexate (a drug used for suppressing the immune system, and often used in rheumatoid arthritis)
- ACE inhibitors and angiotensin receptor blockers (medicines for high blood pressure and heart failure)
- lithium (a medicine used to treat some types of depression)
- diuretics (water tablets)
- cyclosporin or tacrolimus (drugs used for suppressing the immune system)
- digoxin (a medicine for heart failure and irregular heart rhythm)
- minoxidil (a drug used to treat high blood pressure)
- salbutamol tablets or oral solution (a medicine for asthma)
- birth control pills
- hormone replacement therapy

Arcoxia can be taken with low-dose aspirin (acetylsalicylic acid). If you are currently taking low-dose aspirin (acetylsalicylic acid) for prevention of heart attack or stroke, you should not discontinue without consulting your doctor because Arcoxia cannot substitute for aspirin (acetylsalicylic acid) for this purpose. You should be aware that the risk of stomach ulcers is greater if you are taking aspirin with

Arcoxia, and you should not take anti-inflammatory medications or higher doses of aspirin (acetylsalicylic acid) while taking Arcoxia.

### **Pregnancy and breast-feeding**

Arcoxia tablets should not be taken during pregnancy. If you are pregnant or think you could be pregnant, or if you are planning to become pregnant, do not take the tablets. If you become pregnant, stop taking the tablets and consult your doctor. Consult your doctor if you are unsure or need more advice.

It is not known if Arcoxia is excreted in human milk. If you are breast-feeding, or planning to breast-feed, consult your doctor before taking Arcoxia. If you are using Arcoxia, you should not breast-feed.

#### **Use in children**

Arcoxia tablets should not be used in children or adolescents under 16 years of age.

#### **Use in elderly patients**

Arcoxia works equally well in older and younger adult patients. If you are elderly (i.e., over 65 years of age), your doctor will want to appropriately keep a check on you. No dosage adjustment is necessary for elderly patients.

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

Dizziness and sleepiness have been reported in some patients taking Arcoxia.

Do not drive if you experience dizziness or sleepiness.

Do not use any tools or machines if you experience dizziness or sleepiness.

#### **Important information about some of the ingredients of Arcoxia**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **3. HOW TO TAKE ARCOXIA**

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

Take Arcoxia Tablets by mouth once a day. Arcoxia can be taken with or without food.

Do not exceed the recommended dose for treatment of your condition.

#### *Osteoarthritis*

The recommended dose is 60 mg once a day.

#### *Rheumatoid arthritis*

The recommended dose is 90 mg once a day.

#### *Gout*

The recommended dose is 120 mg once a day which should only be used for the acute painful period, limited to a maximum of 8 days treatment.

Doses greater than those recommended for each condition have either not demonstrated additional efficacy or have not been studied. Therefore, the dose stated above for each condition is the maximum recommended dose.

If you have mild liver disease, you should not take more than 60 mg a day. If you have moderate liver disease, you should not take more than 60 mg *every other day*.

Your doctor will have decided which dose is appropriate for you and it is important that you take your tablets as your doctor has instructed.

**If you take more Arcoxia than you should**

You should never take more tablets than the doctor recommends. If you do take too many Arcoxia Tablets, you should seek medical attention immediately.

**If you forget to take Arcoxia**

It is important to keep to the dose the doctor has prescribed. If you miss a dose, do not take an extra dose to make up and just resume your usual schedule the following day.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Arcoxia can cause side effects, although not everybody gets them.

In studies and in general use, the side effects that occurred in patients treated with Arcoxia were as follows:

**Common** (may affect 1 or more persons in 100 but less than 1 in 10)

Weakness and fatigue, dizziness, flu-like illness, diarrhoea, indigestion (dyspepsia), stomach pain or discomfort, heartburn, wind, nausea, changes in blood tests related to the liver, headache, swelling of the legs and/or feet due to fluid retention (oedema) and raised blood pressure, palpitations, bruising.

**Uncommon** (occurring in at least 1 of 1000 and less than 1 of 100 patients treated)

Abdominal bloating, chest pain, swelling of the face, flushing, upper respiratory infection, high blood levels of potassium, changes in blood or urine test relating to the kidney, heart failure, heart attack, stroke, mini-stroke (transient ischaemic attack), abnormal heart rhythm (atrial fibrillation), bowel movement pattern change, constipation, dry mouth, taste alteration, gastroenteritis, stomach ulcer, irritable bowel syndrome, inflammation of the esophagus, mouth ulcers, vomiting, blurred vision, eye irritation and redness, nose bleed, ringing in the ears, vertigo, appetite increase or decrease, weight gain, muscle cramp/spasm, muscle pain/stiffness, inability to sleep, numbness or tingling, sleepiness, anxiety, depression, decrease in mental acuity, breathlessness, cough, skin rash or itchy skin, urinary tract infection.

**Rare** (occurring in at least 1 of 10,000 and less than 1 of 1000 patients treated)

Low blood levels of sodium.

**Very Rare** (may affect less than 1 person in 10,000)

Allergic reactions (which may be serious enough to require immediate medical attention) including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing, bronchospasm (wheezing or shortness of breath), severe skin reactions, inflammation of the stomach lining or stomach ulcers that may become serious and may bleed, liver problems, serious kidney problems, severe increase in blood pressure, confusion, hallucinations.

Consult your doctor if you experience any of the above side effects or any other unusual symptoms you do not understand and particularly if they are persistent, troublesome or getting worse.

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.

It will be helpful if you make a note of what you experienced, when it started and how long it lasted.

## **5. HOW TO STORE ARCOXIA**

Keep your tablets out of the reach and sight of children.

Do not use Arcoxia after the expiry date which is stated on the pack. The expiry date refers to the last day of the month.

Bottles: Keep the container tightly closed.

Blisters: Store in the original package.

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 Arcoxia contains**

The active ingredient in Arcoxia Tablets is etoricoxib. Each film coated tablet contains 60, 90 or 120 mg of etoricoxib.

- The other ingredients are calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate, microcrystalline cellulose (core) and carnauba wax, lactose monohydrate, hypromellose, titanium dioxide, glycerol triacetate. The 60- and 120-mg tablets also contain yellow ferric oxide (E172, colouring agent) and indigo carmine lake (E132, colouring agent) (tablet coating).

### **What Arcoxia looks like and contents of the pack**

Arcoxia Tablets are available in three strengths:

60 mg dark green, apple-shaped, biconvex film coated tablets marked 'ARCOXIA 60' on one side and '200' on the other.

90 mg white, apple-shaped, biconvex film coated tablets marked 'ARCOXIA 90' on one side and '202' on the other.

120 mg pale-green, apple-shaped, biconvex film coated tablets marked 'ARCOXIA 120' on one side and '204' on the other.

Pack sizes of 2, 5, 7, 10, 14, 20, 28, 30, 50, 84, 98 or 100 tablets in blisters; or 30 and 90 tablets in bottles.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

The Marketing Authorisation Holder is Merck Sharp & Dohme Limited, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, UK.

The Manufacturer is Frosst Iberica, S.A., Via Complutense, 140, 28805 Alcala de Henares, Madrid, Spain.

**This medicinal product is authorized in the Member States of the EEA under the following names:**

Austria	Arcoxia 60 mg, 90 mg, 120 mg-Filmtabletten
Belgium	Arcoxia 60 mg, 90 mg, 120 mg, comprimés pelliculés
Czech Rep.	ARCOXIA 60 mg, 90 mg, 120 mg
Cyprus	Arcoxia 60, 90, 120 mg
Denmark	Arcoxia
Estonia	Arcoxia
Finland	Arcoxia 60 mg, 90 mg ja 120 mg tabletti, kalvopäällysteinen
France	Arcoxia comprimé pelliculé
Germany	Arcoxia 60/90/120 mg Filmtabletten
Greece	Arcoxia
Hungary	Arcoxia 60 mg, 90 mg, 120 mg filmtabletta
Iceland	Arcoxia
Ireland	Arcoxia 60, 90 or 120 mg film-coated tablets
Italy	Arcoxia 60, 90, 120 mg compresse rivestite con film
Latvia	Arcoxia 60, 90 un 120 mg apvalkotās tablets
Lithuania	Arcoxia 60, 90, 120 mg plėvele dengtos tabletės
Luxembourg	Arcoxia 60 mg, 90 mg, 120 mg, comprimés pelliculés
Malta	ARCOXIA 60, 90 or 120 mg film-coated tablets
Netherlands	Arcoxia 60, 90, 120
Norway	Arcoxia 60, 90, 120 mg filmdrasjerte tabletter
Poland	Arcoxia
Portugal	Arcoxia 60, 90, 120 mg comprimidos revestidos por película
Slovakia	ARCOXIA 60 mg, 90 mg, 120 mg
Slovenia	Arcoxia 60/90/120 mg filmsko obložene tablete
Spain	Arcoxia 60, 90 y 120 mg comprimidos recubiertos con película
Sweden	Arcoxia 60 mg, 90 mg och 120 mg filmdragerade tabletter
United Kingdom	ARCOXIA 60, 90 or 120 mg film-coated tablets

This leaflet was last approved in (08/2007).