

PACKAGE LEAFLET: INFORMATION FOR THE USER

ARCOXIA[®] 30 mg film-coated tablets
ARCOXIA[®] 60 mg film-coated tablets
ARCOXIA[®] 90 mg film-coated tablets
ARCOXIA[®] 120 mg film-coated tablets

Etoricoxib

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 ARCOXIA is and what it is used for
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1. WHAT ARCOXIA IS AND WHAT IT IS USED FOR

- ARCOXIA is one of a group of medicines called selective COX-2 inhibitors. These belong to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).
- ARCOXIA helps to reduce the pain and swelling (inflammation) in the joints and muscles of people with osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and gout.
- ARCOXIA is also used for the short term treatment of moderate pain after dental surgery.

What is osteoarthritis?

Osteoarthritis is a disease of the joints. It results from the gradual breakdown of cartilage that cushions the ends of the bones. This causes swelling (inflammation), pain, tenderness, stiffness and disability.

What is rheumatoid arthritis?

Rheumatoid arthritis is a long term inflammatory disease of the joints. It causes pain, stiffness, swelling, and increasing loss of movement in the joints it affects. It may also cause inflammation in other areas of the body.

What is gout?

Gout is a disease of sudden, recurring attacks of very painful inflammation and redness in the joints. It is caused by deposits of mineral crystals in the joint.

What is ankylosing spondylitis?

Ankylosing spondylitis is an inflammatory disease of the spine and large joints.

2. BEFORE YOU TAKE ARCOXIA

Do not take ARCOXIA:

- if you are allergic (hypersensitive) to etoricoxib or any of the other ingredients of ARCOXIA (see Further information, section 6)
- if you are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors (see Possible Side Effects, section 4)
- if you have a current stomach ulcer or bleeding in your stomach or intestines
- if you have serious liver disease
- if you have serious kidney disease
- 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, such as Crohn’s Disease, Ulcerative Colitis, or Colitis
- 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

ARCOXIA may not be suitable for you, or you may need to be monitored regularly while taking it if any of the following apply to you:

- You have a history of stomach bleeding or ulcers.
- You are dehydrated, for example by a prolonged bout of vomiting or diarrhoea.
- You have swelling due to fluid retention.
- You have a history of heart failure, or any other form of heart disease.
- You have a history of high blood pressure. ARCOXIA can increase blood pressure in some people, especially in high doses, and your doctor will want to check your blood pressure from time to time.
- You have any history of liver or kidney disease.
- You are being treated for an infection. ARCOXIA can mask or hide a fever, which is a sign of infection.
- You are a woman trying to become pregnant.
- You are elderly (i.e., over 65 years of age).
- You have diabetes, high cholesterol, or are a smoker. These can increase your risk of heart disease.

If you are not sure if any of the above apply to you, **talk to your doctor before taking ARCOXIA** to see if this medicine is suitable for you.

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.

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:

- medicines that thin your blood (anticoagulants), such as warfarin
- rifampicin (an antibiotic)
- methotrexate (a drug used for suppressing the immune system, and often used in rheumatoid arthritis)
- medicines used to help control high blood pressure and heart failure called ACE inhibitors and angiotensin receptor blockers, examples include enalapril and ramipril, and losartan and valsartan
- lithium (a medicine used to treat some types of depression)
- diuretics (water tablets)
- ciclosporin 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
- aspirin, the risk of stomach ulcers is greater if you take ARCOXIA with aspirin.
 - ARCOXIA can be taken with low-dose aspirin. If you are currently taking low-dose aspirin to prevent heart attacks or stroke, you should not stop taking aspirin until you talk to your doctor
 - do not take high dose aspirin or other anti-inflammatory medicines while taking ARCOXIA

Pregnancy and breast-feeding

ARCOXIA tablets must 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 must not breast-feed.

Taking ARCOXIA with food and drink

ARCOXIA tablets may be taken with or without food. The onset of the effect of ARCOXIA may be faster when taken without food.

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

ARCOXIA contains lactose. If you have been told by your doctor that you are unable to tolerate 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.

ARCOXIA Tablets should not be taken by children or adolescents under 16 years of age.

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

Do not take more than the recommended dose for your condition. 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.

Osteoarthritis

The recommended dose is 30 mg once a day, increase to a maximum of 60 mg once a day if needed.

Rheumatoid arthritis

The recommended dose is 90 mg once a day.

Ankylosing spondylitis

The recommended dose is 90 mg once a day.

Acute pain conditions

Etoricoxib should be used only for the acute painful period.

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.

Postoperative dental surgery pain

The recommended dose is 90 mg once daily, limited to a maximum of 3 days treatment.

People with liver problems

- 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 30 mg a day.

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 take ARCOXIA as your doctor has prescribed. If you miss a dose, just resume your usual schedule the following day. Do not take a double dose to make up for the forgotten tablet.

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

4. POSSIBLE SIDE EFFECTS

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

If you develop any of these signs you should stop ARCOXIA and talk to your doctor immediately:

- shortness of breath, chest pains, or ankle swelling appear or if they get worse
- yellowing of the skin and eyes (jaundice) – these are signs of liver problems

- severe or continual stomach pain or your stools become black
- an allergic reaction- which can include skin problems such as ulcers or blistering, or swelling of the face, lips, tongue, or throat which may cause difficulty in breathing

The frequency of possible side effects listed below is defined using the following convention:

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).

The following side effects can occur during treatment with ARCOXIA:

Common

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

Uncommon

Stomach or bowel bloating, chest pain, heart failure, feeling of tightness, pressure or heaviness in the chest (angina pectoris), heart attack, stroke, mini-stroke (transient ischaemic attack), abnormal heart rhythm (atrial fibrillation), upper respiratory infection, high levels of potassium in your blood, changes in blood or urine tests relating to your kidney, changes in your bowel habits including constipation, dry mouth, mouth ulcers, taste alteration, gastroenteritis, gastritis, stomach ulcer, being sick (vomiting), irritable bowel syndrome, inflammation of the oesophagus, blurred vision, eye irritation and redness, nose bleed, ringing in the ears, vertigo, appetite increases or decreases, weight gain, muscle cramp/spasm, muscle pain/stiffness, inability to sleep, sleepiness, numbness or tingling, anxiety, depression, decreases in mental sharpness, breathlessness, cough, swelling of the face, flushing, skin rash or itchy skin, urinary tract infection, platelets decreased, decreased number of red blood cells, decreased number of white blood cells.

Rare

Low blood levels of sodium, redness of the skin.

Very Rare

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 can become serious and may lead to bleeding, liver problems, serious kidney problems, severe increase in blood pressure, confusion, seeing, feeling or hearing things that are not there (hallucinations).

Not known

Yellowing of the skin and eyes (jaundice), liver failure, inflammation of the pancreas, fast heart rate, irregular heart rhythm (arrhythmia), restlessness, inflammation of the blood vessels.

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 ARCOXIA

Keep 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 in order to protect from moisture.

Blisters: Store in the original package in order to protect 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 ARCOXIA contains

- The active substance is etoricoxib. Each film coated tablet contains 30, 60, 90 or 120 mg of etoricoxib.
- The other ingredients are:
Core: calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate, microcrystalline cellulose.
Tablet coating: carnauba wax, lactose monohydrate, hypromellose, titanium dioxide (E171), triacetin.
The 30-, 60- and 120-mg tablets also contain yellow ferric oxide (E172, colouring agent) and indigo carmine lake (E132, colouring agent).

What ARCOXIA looks like and contents of the pack

ARCOXIA Tablets are available in four strengths:

30 mg blue-green, apple-shaped, biconvex film coated tablets marked 'ACX 30' on one side and '101' on the other.

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:

30 mg:

Pack sizes of 2, 7, 14, 20, 28 tablets or multi-packs containing 98 (2 packs of 49) tablets in blisters.

60, 90, 120 mg:

Pack sizes of 2, 5, 7, 10, 14, 20, 28, 30, 50, 84, 100 tablets or multi-packs containing 98 (2 packs of 49) tablets in blisters; or 30 and 90 tablets in bottles with desiccant containers. The desiccant (one or two containers) in the bottle, used to keep the tablets dry, should not be swallowed.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder in the UK and Malta is Merck Sharp & Dohme Ltd, Hertford Road, Hoddesdon, Herts, EN11 9BU, UK.

The Marketing Authorisation Holder in Ireland is Merck Sharp & Dohme Ireland (Human Health) Ltd, Pelham House, South County Business Park, Leopardstown, Dublin 18, Ireland.

Manufacturer: Merck Sharp & Dohme BV, Waarderweg 39, 2031 BN Haarlem, The Netherlands.

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

Belgium, Luxemburg	Arcoxia 30 mg, 60 mg, 90 mg, 120 mg, comprimés pelliculés
Denmark, Estonia, Iceland, Norway	Arcoxia
Malta, Ireland, United Kingdom	ARCOXIA 30, 60, 90 or 120 mg film-coated tablets
Austria	Arcoxia 30 mg, 60 mg, 90 mg, 120 mg-Filmtabletten
Czech Rep.	ARCOXIA 30 mg, 60 mg, 90 mg, 120 mg, potahované tablety
Cyprus	ARCOXIA 30, 60, 90, 120 mg
Finland	Arcoxia 30, 60, 90 ja 120 mg tabletti, kalvopäällysteinen
France	ARCOXIA 30, 60, 90 mg, comprimé pelliculé
Germany	ARCOXIA 30/60/90/120 mg Filmtabletten
Greece	ARCOXIA 30 mg, 60 mg, 90 mg, 120 mg film-coated tablets
Hungary	Arcoxia 30 mg, 60 mg, 90 mg, 120 mg filmtabletta
Italy	ARCOXIA 30, 60, 90, 120 mg compresse rivestite con film
Latvia	Arcoxia 30 mg, 60 mg, 90 mg un 120 mg apvalkotās tableti
Lithuania	Arcoxia 30, 60, 90, 120 mg plėvele dengtos tabletės
Netherlands	Arcoxia 30 mg, 60 mg, 90 mg, 120 mg, filmomhulde tabletten
Poland	ARCOXIA 30 mg, 60 mg, 90 mg, 120 mg tabletki powlekane
Portugal	ARCOXIA 30 mg, 60 mg, 90 mg, 120 mg comprimidos revestidos por película
Slovakia	ARCOXIA 30 mg, 60 mg, 90 mg, 120 mg
Slovenia	Arcoxia 30/60/90/120 mg filmsko obložene tablete
Spain	ARCOXIA 30, 60, 90 y 120 mg comprimidos recubiertos con película
Sweden	Arcoxia 30 mg, 60 mg, 90 mg och 120 mg filmdragerade tabletter

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