

ARCOXIA® TABLET

Etoricoxib (30 mg, 60 mg, 90 mg, 120 mg)

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What Arcoxia tablet is used for

Your doctor has prescribed Arcoxia tablet for:

- treatment of osteoarthritis
- treatment of rheumatoid arthritis
- treatment of ankylosing spondylitis
- chronic low back pain (30 mg and 60 mg only)
- treatment of acute pain after minor dental procedures
- treatment of menstrual pain
- treatment of gout attacks

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

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

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

Gout is a disorder characterized by sudden, recurring attacks of pain and inflammation in one or

more joints.

You may obtain further information from your doctor or pharmacist, who have more detailed information.

How Arcoxia tablet works

Arcoxia tablet is a member of a group of medicines called selective COX-2 inhibitors that are used to reduce pain and inflammation. Arcoxia tablet is not a narcotic.

Before you take Arcoxia tablet

- When you must not take it

Do not take Arcoxia tablet if you:

- are allergic to any of its ingredients
- have had heart failure, a heart attack, bypass surgery, chest pain, narrow or blocked arteries of the extremities, a stroke or mini stroke
- have high blood pressure that has not been controlled by treatment

- Before you start to take it

Tell your doctor about any medical problems or allergies you have now or have had, including:

- history of angina, heart attack or a blocked artery in your heart
- narrow or blocked arteries of the extremities
- kidney disease
- liver disease
- dehydration, for example by a prolonged bout of vomiting or diarrhea.
- have or have had ulceration, bleeding or perforation of your stomach or intestines
- heart failure
- high blood pressure
- swelling due to fluid retention
- an allergic reaction to aspirin or other anti-inflammatory

- medicines (commonly known as NSAIDs).
- a history of stroke or mini stroke
- conditions which increase your risk of coronary artery disease or atherosclerosis such as high blood pressure, diabetes, high cholesterol or smoking.
- being treated for an infection. Arcoxia tablet can mask or hide a fever, which is a sign of infection.
- have had asthma, nasal inflammation, and/or itching or hives caused by Aspirin or NSAIDs.
- suffering from dyspepsia (indigestion).

Etoricoxib may cause severe skin reactions. Symptoms may include skin rash, blisters and peeling of the skin. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

Use in children

Arcoxia tablet has not been adequately studied in children. Therefore, Arcoxia tablet should not be given to children.

Use in the elderly

Arcoxia tablet works equally well in older and younger adult patients. Adverse experiences may occur at a higher incidence in older patients compared to younger 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 older patients.

Use in pregnancy and breastfeeding

Tell your doctor if you are:

- Arcoxia tablet may cause fetal harm and should not be

used by a woman who is attempting to become pregnant or becomes pregnant during treatment.

- Breastfeeding or plan to breastfeed.

- Taking other medicines

You should always tell your doctor about all medicines that you are taking or plan to take, including those obtained without a prescription.

Your doctor may want to check that your medicines are working properly if you are taking:

- warfarin (a blood thinner)
- rifampin (an antibiotic)
- diuretics (water tablets)
- ACE inhibitors and angiotensin receptor blockers (medicines used for high blood pressure and heart failure)
- lithium (a medicine used to treat a certain type of depression)
- birth control pills
- hormone replacement therapy
- methotrexate (a medicine used for suppressing the immune system).

Arcoxia tablet can be taken with low-dose aspirin. If you are currently taking low-dose aspirin for prevention of heart attack or stroke, you should not discontinue without consulting your doctor because Arcoxia tablet cannot substitute for aspirin for this purpose.

How to take Arcoxia tablet

- How much to take

Arcoxia tablet should be taken once a day. You may take Arcoxia tablet with or without food.

Your doctor will decide what dose of Arcoxia tablet you should take and how long you should take it.

For treatment of osteoarthritis:

The recommended dose is 30mg or 60 mg once a day.

For treatment of rheumatoid arthritis:

The recommended dose is 60 mg once a day, and may increase to 90 mg once a day if needed.

For treatment of ankylosing spondylitis:

The recommended dose is 60 mg once a day, and may increase to 90 mg once a day if needed.

Chronic low back pain:

The recommended dose is 60 mg once daily.

Acute pain conditions

The recommended dose is 90mg or 120mg once daily. Arcoxia should be used only for the acute period limited to a maximum of 8 days.

For the relief of gout attacks and the treatment of menstrual pain:

- The recommended dose is 120 mg once a day which should only be used for the acute painful period.

For the relief of pain after minor dental procedures

- The recommended dose is 90mg once a day.

Doses greater than those recommended for each condition have either not demonstrated additional efficacy or have not been studied. Therefore, the daily doses stated above for each condition should not be exceeded.

If you have mild or moderate liverdisease, your doctor might prescribe you a lower dose or recommend that you do not take Arcoxia.

- When to take it

Use as directed by your doctor or pharmacist.

- How long to take it

Continue taking Arcoxia tablet for as long as your doctor recommends.

- If you forget to take it

Try to take Arcoxia tablet as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule the following day.

- If you take too much

(overdose) If you take more than the prescribed dosage, contact your doctor immediately.

While you are taking Arcoxia tablet

- Things you must do

Consult your doctor if:

- Any of the following symptoms appear or worsen: shortness of breath, chest pains or ankle swelling. Stop your treatment with Arcoxia tablet and consult a doctor, as soon as is practical.
- You have kidney, liver or heart disease, your doctor will want to appropriately keep a check on you.
- You develop any symptoms that could indicate a severe allergic reaction such as inability to breathe or a serious skin reaction, 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.

Arcoxia tablet 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.

- Things you must not do

Do not share Arcoxia tablet with anyone else; it was prescribed only for you.

Do not take Arcoxia tablet for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.

- Things to be careful of

Be careful driving or operating machinery until you know how Arcoxia affects you.

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.

Side effects

Any medicine may have unintended or undesirable effects, so-called side effects.

Like all prescription medicines, Arcoxia tablet may cause side effects.

Some of the side effects reported in the studies included:

- dizziness,
- swelling of the legs and/or feet,
- weakness and fatigue,
- high blood pressure,
- nausea,
- heartburn,
- upset stomach,
- headache
- dry socket (inflammation and pain after a tooth extraction)

Additionally, the following have been reported:

- allergic reactions (which maybe serious enough to require immediate medical attention) including swelling of the face, lips, tongue, and/or throat which may cause difficulty

inbreathing or swallowing, wheezing, rash, itching and hives;

- redness of the skin,
- severe skin reactions which may occur without warning;
- taste alteration,
- abnormal rhythm of the heart,
- heart failure,
- palpitations,
- feeling of tightness, pressure or heaviness in the chest,
- stomach pain,
- stomach ulcers that may become serious and may bleed and may occur at any time during use and without warning,
- vomiting,
- liver problems including liver failure, yellowing of the skin and eyes (jaundice),
- serious kidney problems,
- high levels of potassium in your blood,
- insomnia,
- anxiety,
- depression,
- restlessness,
- drowsiness,
- mouth ulcers,
- diarrhea,
- severe increase in blood pressure,
- confusion,
- hallucinations,
- platelets decreased,
- blurred vision,
- blood clots in the blood vessels of the lung and/or leg
- bleeding within the brain.

In clinical studies, the risk of developing ulcers while taking Arcoxia tablet was lower than with NSAIDs.

Other side effects may also occur rarely, and as with any prescription medicine, some side effects may be serious. Ask your doctor or pharmacist for more information. Both have a more complete list of side effects. Tell your doctor or pharmacist promptly about these or any other

unusual symptoms.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal

- Storage

Store at 30 °C (86 °F). Store in the original package. Protect from moisture and light.

Keep Arcoxia tablet and all medicines safely away from children.

Do not use this medicine after the month and year shown by the four numbers following EX (or EXP) on the container. The first two numbers indicate the month; the last two numbers indicate the year.

- Disposal

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.

Product Description

- What it looks like

- Arcoxia 30mg: Blue-green apple-shape biconvex film coated tablets debossed ACX 30 on one side and 101 on the other side
- Arcoxia 60mg: Dark green apple-shape biconvex film coated tablets debossed Arcoxia 60 on one side and 200 on the other side
- Arcoxia 90mg: White apple-shape biconvex film coated

- tablets debossed *ARCOXIA* 90 on one side and 202 on the other side
- Arcoxia 120mg: Pale green apple-shape biconvex film coated tablets debossed Arcoxia 120 on one side and 204 on the other side

- Ingredients

- Active ingredient: Etoricoxib

- Inactive ingredients: Calcium hydrogen phosphate anhydrous; microcrystalline cellulose; croscarmellose sodium; hypromellose; magnesium stearate; lactose monohydrate; titanium dioxide; glycerol triacetate and carnauba wax. The 30 mg, 60 mg and 120 mg tablets also contain yellow ferric oxide and FD&C Blue #2 (indigo carmine lake).

- MAL number Arcoxia 30 mg tablet: MAL12065063ACRZ

Arcoxia 60 mg tablet:
MAL12065082ACRZ

Arcoxia 90 mg tablet:
MAL12065065ACRZ

Arcoxia 120 mg tablet:
MAL12065084ACRZ

Product Manufacturer

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Product Registration Holder

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