

ARBICOX FILM-COATED TABLETS

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

What is in this leaflet

1. What Arbicox is used for
2. How Arbicox works
3. Before you use Arbicox
4. How to use Arbicox
5. While you are using it
6. Side effects
7. Storage and Disposal of Arbicox
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of RiMUP revision
11. Serial Number

What Arbicox is used for

Your doctor has prescribed Arbicox 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 Arbicox works

Arbicox is a member of a group of medicines called selective COX-2

inhibitors that are used to reduce pain and inflammation. Arbicox is not a narcotic.

Before you use Arbicox

- When you must not use it

Do not take Arbicox 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 use 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. Arbicox 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

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

Use in the elderly

Arbicox 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:

- Pregnant, trying to get pregnant or think you may be pregnant. Arbicox 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)

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Arbicox 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 Arbicox cannot substitute for aspirin for this purpose.

How to use Arbicox

- How much to use

Arbicox should be taken once a day. You may take Arbicox with or without food. Your doctor will decide what dose of Arbicox you should take and how long you should take it.

For treatment of osteoarthritis:

The recommended dose is 30 mg 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 90 mg or 120 mg once daily. Arbicox 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 90 mg 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 liver disease, your doctor might prescribe you a lower dose or recommend that you do not take Arbicox.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Arbicox for as long as your doctor recommends.

- If you forget to use it

Try to take Arbicox as prescribed.

However, if you miss a dose, do not take an extra dose. Just resume your usual schedule the following day.

- If you use too much (overdose)

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

While you are using Arbicox

- 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 Arbicox 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.

Arbicox 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 Arbicox with anyone else; it was prescribed only for you.

Do not take Arbicox 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 Arbicox affects you.

Arbicox 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, Arbicox 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 in breathing or swallowing, wheezing, rash, itching and hives
- redness of the skin
- severe skin reactions which may occur without warning

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- 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 Arbicox 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 nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Arbicox

- Storage

Store below 30 °C. Store in the original package in order to protect from moisture.

Keep out of the reach and sight of children.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

- 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

30 mg film-coated tablets: white or almost white, round, slightly biconvex, film coated tablets with beveled edges.

60 mg film-coated tablets: slightly brownish yellow, round, biconvex, film coated tablets with beveled edges, engraved with mark "60" on one side of the tablet.

90 mg film-coated tablets: pink, round, biconvex, film coated tablets with beveled edges, engraved with mark "90" on one side of the tablet.

120 mg film-coated tablets: brownish red, round, slightly biconvex, film coated tablets with beveled edges, scored on one side of the tablet. The score line is not intended for breaking the tablet into equal halves, it could be split for the ease of swallowing.

- Ingredients

- Active ingredient

Each film-coated tablet contains 30, 60, 90 or 120 mg etoricoxib.

- Inactive ingredients

• Tablet Core:

Cellulose, microcrystalline, Calcium hydrogen phosphate, Croscarmellose sodium, Sodium stearyl fumarate, Silica, colloidal anhydrous.

• Film coating:

Opadry 85F28751 II white (polyvinyl alcohol, titanium dioxide (E171), macrogol 3000, talc) 60 mg tablets also contain ferric oxide yellow E172. 90 mg and 120 mg tablets also contain ferric oxide red E172.

Presentation

Blister (Aluminium (OPA/Al/PVC) / Aluminium): 30 film-coated tablets, in a box.

- MAL numbers:

30mg: MAL25026023AZ
60mg: MAL25026022AZ
90mg: MAL25026020AZ
120mg: MAL25026018AZ

Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Product Registration Holder

Pahang Pharmacy Sdn. Bhd. Lot 5979, Jalan Teratai, 5 ½ Miles off Jalan Meru, 41050 Klang, Selangor, Malaysia.

Date of revision

12/05/2025

Serial Number

NPRA (R2) 23/174