

AXCEL ETORICOXIB-90MG TABLET

Etoricoxib 90mg

What Is In This Leaflet

1. What Axcel Etoricoxib-90mg Tablet is used for.
2. How Axcel Etoricoxib-90mg Tablet works.
3. Before you use Axcel Etoricoxib-90mg Tablet.
4. How to use Axcel Etoricoxib-90mg Tablet.
5. While you are using it.
6. Side effects.
7. Storage and disposal of Axcel Etoricoxib-90mg Tablet.
8. Product description.
9. Manufacturer and Product Registration Holder.
10. Date of revision.

What Axcel Etoricoxib-90mg Tablet Is Used For

It helps to reduce the pain and swelling (inflammation) in the joints and muscles of people with osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and gout. It is also used for the treatment of acute pain, including that related to menstrual pain and minor dental procedures.

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.

How Axcel Etoricoxib-90mg Tablet Works

Etoricoxib 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), that exhibits anti-inflammatory, analgesic, and antipyretic activities.

Before You Use Axcel Etoricoxib-90mg Tablet

When you must not use it

You must not use Axcel Etoricoxib-90mg Tablet if you:

- if you are allergic (hypersensitive) to etoricoxib or any of the other ingredients of Axcel Etoricoxib-90mg Tablet
- if you are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors
- 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
- 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.

Before you start to use it

Ask a doctor or pharmacist if:

- 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. Etoricoxib 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. Etoricoxib 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 Axcel Etoricoxib-90mg Tablet to see if this medicine is suitable for you.

Taking other medicines

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 Axcel Etoricoxib-90mg Tablet:

- medicines that thin your blood (anticoagulants), such as warfarin
- rifampicin (an antibiotic)
- methotrexate (a drug used for suppressing the immune system,

AXCEL ETORICOXIB-90MG TABLET

Etoricoxib 90mg

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)
- digoxin (a medicine for heart failure and irregular heart rhythm)
- birth control pills
- hormone replacement therapy
- aspirin, the risk of stomach ulcers is greater if you take Axcel Etoricoxib-90mg Tablet with aspirin.
- Axcel Etoricoxib-90mg Tablet 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 Axcel Etoricoxib-90mg Tablet

Pregnancy and breast-feeding

Axcel Etoricoxib-90mg Tablet 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 Axcel Etoricoxib-90mg Tablet is excreted in human milk. If you are breast-feeding, or planning to breast-feed, consult your doctor before taking Axcel Etoricoxib-90mg Tablet. If you are using Axcel Etoricoxib-90mg Tablet, you must not breast-feed.

Axcel Etoricoxib-90mg Tablet with food and drink

The onset of the effect of Axcel Etoricoxib-90mg Tablet may be faster when taken without food.

Driving and using machines

Dizziness and sleepiness have been reported in some patients taking Axcel Etoricoxib-90mg Tablet.

Do not drive if you experience dizziness or sleepiness.

How To Use Axcel Etoricoxib-90mg Tablet

Axcel Etoricoxib-90mg Tablet Tablets should not be taken by children or adolescents under 16 years of age.

How much to use

Osteoarthritis

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

Rheumatoid arthritis

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

Ankylosing spondylitis

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

Acute pain conditions

Etoricoxib should be used only for the acute painful period.

Acute Gouty Arthritis and Primary Dysmenorrhea

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

Minor Dental Procedures

The recommended dose is 90mg once a day which should only be used for the acute painful period, limited to a maximum of 8 days treatment.

When to use it

Take Axcel Etoricoxib-90mg Tablet Tablets by mouth once a day. Axcel Etoricoxib-90mg Tablet can be taken with or without food.

People with liver problems

Follow recommendations and advices from your doctor.

If you forget to use it

It is important to take Axcel Etoricoxib-90mg Tablet 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 use too much (overdose)

You should never take more tablets than the doctor recommends. If you do take too many Axcel Etoricoxib-90mg Tablet tablets, you should seek medical attention immediately.

While You Are Using It

Things you must not do

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 Axcel Etoricoxib-90mg Tablet for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.

Side Effects

If you develop any of these signs you should stop Axcel Etoricoxib-90mg Tablet 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

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)].

AXCEL ETORICOXIB-90MG TABLET

Etoricoxib 90mg

Storage And Disposal Of Axcel Etoricoxib-90mg Tablet

Storage

Keep Axcel Etoricoxib-90mg Tablet out of reach of children.

Store below 30°C. Keep container well closed and protect from light.

Disposal

Do not use after the expiry date stated on the label.

Do not throw them away with your normal household water or waste. This will help to protect the environment.

Product Description

What it looks like

Axcel Etoricoxib-90mg Tablet is white coloured, round shape with 8.0 diameter, biconvex, embossed with 'Kotra' logo on one side and breakline on the other side.

Ingredients

Active Ingredient:

Etoricoxib

Inactive Ingredients:

Dicalcium phosphate anhydrous granular, microcrystalline cellulose, povidone K30, croscarmellose sodium, magnesium stearate, opadry II white, purified water.

MAL Number

MAL17107080AZ

Manufacturer And Product Registration Holder

KOTRA PHARMA (M) SDN BHD
No. 1, 2 & 3, Jalan TTC 12,
Cheng Industrial Estate,
75250 Melaka, Malaysia.

Date Of Revision

19/07/2022

Serial Number

NPRA(R2/1)220708/911