

ETORICOXIB intega Film Coated Tablet

Etoricoxib 60mg, 90mg and 120mg

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What ETORICOXIB intega Tablet is used for

ETORICOXIB intega Tablet 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 ETORICOXIB intega 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 reduces pain and inflammation.

Before you use ETORICOXIB intega Tablet

When you must not use it

You must not use ETORICOXIB intega Tablet if you:

- are allergic to etoricoxib or any of the other ingredients of ETORICOXIB intega Tablet
- have 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 is not under control
- have a current stomach ulcer or bleeding in your stomach or intestines
- have serious liver disease
- have serious kidney disease
- experience wheezing, nasal inflammation, and/or itching or hives caused by non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin
- are or could be pregnant or are breast-feeding

- are under 16 years of age
- have inflammatory bowel disease, such as Crohn's Disease, Ulcerative Colitis, or Colitis

Before you start to use it

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

- History of stomach bleeding or ulcers.
- Dehydrated, for example by a prolonged bout of vomiting or diarrhea.
- Swelling due to fluid retention.
- History of heart failure, or any other form of heart disease.
- 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.
- 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 (over 65 years of age).
- You have diabetes, high cholesterol, or are a smoker. These can increase your risk of heart disease.

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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.

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

Pregnancy and breast-feeding
ETORICOXIB intega 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 ETORICOXIB intega Tablet is excreted in human milk. If you are breast-feeding, or planning to breast-feed, consult your doctor before taking ETORICOXIB intega Tablet. If you are using ETORICOXIB intega Tablet, you must not breast-feed.

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 ETORICOXIB intega Tablet:

- medicines that thin your blood (anticoagulants), such as warfarin
- medicines used to help control high

blood pressure and heart failure called ACE inhibitors and angiotensin receptor blockers, examples include enalapril, losartan and valsartan

- aspirin, the risk of stomach ulcers is greater if you take ETORICOXIB intega Tablet with aspirin
 - ETORICOXIB intega 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 ETORICOXIB intega Tablet
- ciclosporin or tacrolimus (drugs used for suppressing the immune system)
- lithium (a medicine used to treat some types of depression)
- methotrexate (a drug used for suppressing the immune system and often used in rheumatoid arthritis)
- birth control pills (the combination may increase your risk of side effects)
- hormone replacement therapy (the combination may increase your risk of side effects)
- diuretics (water tablets)
- 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)
- rifampicin (an antibiotic)

How to use ETORICOXIB intega Tablet

ETORICOXIB intega Tablet 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. Do not exceed 60mg daily.

Rheumatoid arthritis

The recommended dose is 60mg once a day, and may increase to 90mg once a day if needed. Do not exceed 90mg daily.

Ankylosing spondylitis

The recommended dose is 60mg once a day, and may increase to 90mg once a day if needed. Do not exceed 90mg daily.

Acute pain conditions

Etoricoxib should be used only for the acute painful period. Do not exceed 120mg daily.

Acute Gouty Arthritis and Primary Dysmenorrhea

The recommended dose is 120mg once daily. Etoricoxib 120mg should only be used for the acute symptomatic period, limited to a maximum of 8 days treatment. Do not exceed 120mg daily.

Minor Dental Procedures

The recommended dose is 90mg once daily. Etoricoxib 90mg should be used only for the acute symptomatic period, limited to a maximum of 8 days treatment. The dose for minor dental procedures should not exceed 90mg daily.

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When to use it

Take ETORICOXIB *intega* Tablet by mouth once a day. ETORICOXIB *intega* Tablet can be taken with or without food. People with liver problems - Follow recommendations and advice from your doctor.

How long to use it

Continue taking ETORICOXIB *intega* Tablet for as long as your doctor recommends. Your doctor will use the lowest dose that controls your pain and you should not take ETORICOXIB *intega* Tablet for longer than recommended.

If you forget to use it

It is important to take ETORICOXIB *intega* 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 tablets, you should seek medical attention immediately.

While You Are Using It

Things you must do

If you develop any of these signs you should stop ETORICOXIB *intega* 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 continuous 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

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 ETORICOXIB *intega* 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

Driving and using machines

Dizziness and sleepiness have been reported in some patients taking ETORICOXIB *intega* Tablet. Do not drive if you experience dizziness or sleepiness.

Side Effects

Any medicine may have unintended or side effects. The following side effects can occur during treatment with

ETORICOXIB *intega* Tablet:

- Stomach pain
- dry socket (inflammation and pain after a tooth extraction)
- swelling of the legs and/or feet due to fluid retention (oedema)
- dizziness, headache
- palpitations (fast or irregular heartbeat), irregular heart rhythm (arrhythmia)
- increased blood pressure
- wheezing or shortness of breath (bronchospasms)
- constipation, wind (excessive gas), gastritis (inflammation of the lining of the stomach), heartburn, diarrhoea,

indigestion (dyspepsia)/stomach discomfort, nausea, being sick (vomiting), inflammation of the oesophagus, mouth ulcers

- changes in blood tests related to your liver bruising
- weakness and fatigue, flu-like illness

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 of ETORICOXIB *intega* Tablet

Storage

Keep ETORICOXIB *intega* Tablet out of reach of children.

Store below 30°C.

Store in the original package in order to protect from moisture.

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

ETORICOXIB *intega* 60mg Tablet: dark green apple-shape biconvex film-coated tablets debossed with “60” on one side and plain on the other side

ETORICOXIB *intega* 90mg Tablet: White apple-shape biconvex film-coated tablets debossed “90” on one side and plain on the other side

ETORICOXIB intega Film Coated Tablet

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ETORICOXIB intega 120mg
Tablet: Pale- green apple-
shape biconvex film-coated
tablets debossed "120" on
one side and plain on the
other side.

Date of revision
15 Feb 2024

Serial Number
NPRA (R2) 21/073

Ingredients

Active Ingredient
Etoricoxib

Inactive Ingredients:

Microcrystalline Cellulose;
calcium hydrogen phosphate
anhydrous; croscarmellose
sodium; magnesium stearate.

*Coating material 60mg and
120mg*

Polyvinyl alcohol, titanium
dioxide; glycerol monostearate;
indigo carmine aluminium lake;
yellow iron oxide; talc and
sodium laurilsulfate.

Coating material 90mg

Polyvinyl alcohol, titanium
dioxide; glycerol
monostearate; talc and
sodium laurilsulfate.

MAL Number(s)

ETORICOXIB intega 60mg

Tablets:

MAL21106024ACZ

ETORICOXIB intega 90mg

Tablets:

MAL21106025ACZ

ETORICOXIB intega 120mg

Tablets:

MAL21106026ACZ

Manufacturer

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Larissa Industrial Area, P.O. Box
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Product Registration Holder

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Persekutuan Kuala Lumpur