

ETORIGEN FILM-COATED TABLETS

Etoricoxib (90 mg, 120 mg)

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What Etorigen is used for

Etorigen is indicated for use as below:

- Acute and chronic treatment of the signs and symptoms of bone and joint pain, as well as the inflammation of joint. - Treatment of spine and joints - Treatment of acute pain, swelling, redness, and tenderness in joints, most often in big toe.
- Treatment of acute pain, including that related to common menstrual cramp and minor dental procedures.

How Etorigen works

Etorigen is one of a group of medicines called selective COX-2 inhibitors.

These belong to a family of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs).

Before you use Etorigen

-When you must not use it Do not take Etorigen 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 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. Etorigen 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 Etorigen tablet has not been adequately studied in children. Therefore, Etorigen tablet should not be given to children.

Use in the elderly Etorigen 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: - Etorigen 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

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(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).

Etorigen 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 Etorigen tablet cannot substitute for aspirin for this purpose.

How to use Etorigen

-How much to use Etorigen tablet should be taken once a day. You may take Etorigen tablet with or without food.

Your doctor will decide what dose of Etorigen tablet 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 90 mg once a day.

For treatment of ankylosing spondylitis:

-The recommended dose is 90 mg once a day.

Acute pain conditions -The recommended dose is 90mg or 120mg once daily. Etorigen 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 liver disease, your doctor might prescribe you a lower dose or recommend that you do not take Etorigen.

-When to use it Use as directed by your doctor or pharmacist.

-If you use too much (overdose)

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

-If you forget to take Etorigen It is important to take Etorigen 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

medicine, ask your doctor or pharmacist.

While you are using it

-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 Etorigen 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.

Etorigen 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 Etorigen tablet with anyone else; it was prescribed only for you. -Do not take Etorigen tablet for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.

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= Things to be careful of
-Be careful driving or operating machinery until you know how Etorigen affects you.

= Etorigen 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, Etorigen 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 may be 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; -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.

In clinical studies, the risk of developing ulcers while taking Etorigen 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.

Reporting of side effects: If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

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 7] Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Etorigen

-Storage -Keep this medicine out of the sight and reach of children. -Store below 30°C. Store in the original package in order to protect from light. -Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. -Disposal Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

-What it looks like **Etorigen**

90 mg: Circular, white film- coated tablets

Etorigen 120 mg: Circular, green film-coated tablets

-Ingredients *Active ingredient(s):*

Etoricoxib *Inactive*

ingredients:

Etorigen 90 mg

Calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate, microcrystalline cellulose, lactose monohydrate, hypromellose, titanium dioxide (E171) and triacetin.

Etorigen 120 mg

Calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate, microcrystalline cellulose,

(RiMUP)

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lactose monohydrate,
hypromellose, titanium dioxide
(E171), triacetin, indigo
carmine aluminium lake (E132)
and yellow iron oxide (E172).

-MAL number

Etorigen 90mg film-coated
tablets: MAL22096022AZ

Etorigen 120mg film-coated
tablets: MAL22096023AZ

Manufacturer

Atlantic Pharma – Produções
Farmacêuticas, S.A.
Rua de Tapada Grande 2,
Abrunheira, Sintra
2710-228 Portugal.

Product Registration Holder

Activ Pharma Sdn. Bhd.
(1170576-P)
No. 18, Jalan Astaka U8/88A,
Seksyen U8, Bukit Jelutong,
40150 Shah Alam, Selangor,
Malaysia

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17/02/2025

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