

ETORICAN 30MG, 60MG, 90MG, 120MG FILM-COATED TABLETS

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

What is in this leaflet 1. What ETORICAN is used for 2. How ETORICAN works 3. Before you use ETORICAN 4. How to use ETORICAN 5. While you are using it 6. Side effects 7. Storage and Disposal of ETORICAN 8. Product Description 9. Manufacturer and Product Registration Holder 10. Date of Revision 11. Serial Number	crystals in the joint. <i>What is ankylosing spondylitis?</i> Ankylosing spondylitis is an inflammatory disease of the spine and large joints. How ETORICAN works ETORICAN 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 ETORICAN <i>- When you must not use it</i> You must not use ETORICAN if you: • are allergic to etoricoxib or any of the other ingredients of ETORICAN • 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 <i>- Before you start to use it</i> 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. 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 ETORICAN to see if this medicine is suitable for you. <i>Pregnancy and breast-feeding</i> ETORICAN 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.
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It is not known if ETORICAN is excreted in human milk. If you are breastfeeding, or planning to breastfeed, consult your doctor before taking ETORICAN. If you are using ETORICAN, 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 ETORICAN:

- 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 ETORICAN with aspirin
 - ETORICAN 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 ETORICAN.
- 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 ETORICAN

ETORICAN 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 90 mg once daily. Etoricoxib 90 mg 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 90 mg daily.

- When to use it

Take ETORICAN by mouth once a day. ETORICAN 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 ETORICAN for as long as your doctor recommends. Your doctor will use the lowest dose that controls your pain, and you should not take ETORICAN for longer than recommended.

- If you forget to use it

It is important to take ETORICAN 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 ETORICAN 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

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- 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 ETORICAN 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 ETORICAN. 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 ETORICAN:

- 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 ETORICAN

- Storage

Keep ETORICAN 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

ETORICAN 30mg: blue green apple-shaped biconvex film-coated tablets debossed with “30” on one side and plain on the other side.

ETORICAN 60mg: dark green apple-shape biconvex film-coated tablets debossed with “60” on one side and plain on the other side.

ETORICAN 90mg: White apple-shape biconvex film-coated tablets debossed “90” on one side and plain on the other side.

ETORICAN 120mg: Pale- green apple shape biconvex film-coated tablets debossed “120” on one side and plain on the other side.

- Ingredients

- Active ingredient
Etoricoxib

- Inactive ingredients

Microcrystalline Cellulose; Calcium hydrogen phosphate; Croscarmellose Sodium; Magnesium Stearate.

Coating material

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

- MAL Number(s):

ETORICAN 30mg film-coated tablets: MALXXXXXXXXXX

ETORICAN 60mg film-coated tablets: MALXXXXXXXXXX

ETORICAN 90mg film-coated tablets: MALXXXXXXXXXX

ETORICAN 120mg film-coated tablets: MALXXXXXXXXXX

Manufacturer

Rontis Hellas Medical and Pharmaceutical Products S.A.
P.O. Box 3012 Larisa Industrial Area, Larisa 41004 GREECE.

Product Registration Holder

Generic Health Sdn. Bhd.
Upper Penthouse, Wisma RKT, No.2, Jalan Raja Abdullah, Off Jalan Sultan Ismail, 50600 Kuala Lumpur, Malaysia.

Date of Revision

10 January 2022

Serial Number

NPRA (R2) 21/154