

PACKAGE LEAFLET

Package leaflet: Information for the patient

Etoricoxib 30 mg Film-coated Tablets
Etoricoxib 60 mg Film-coated Tablets
Etoricoxib 90 mg Film-coated Tablets
Etoricoxib 120 mg Film-coated Tablets

(etoricoxib)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Etoricoxib is and what it is used for
2. What you need to know before you take Etoricoxib
3. How to take Etoricoxib
4. Possible side effects
5. How to store Etoricoxib
6. Contents of the pack and other information

1. What Etoricoxib is and what it is used for

Etoricoxib contains the active substance etoricoxib which is one of a group of medicines called selective cyclooxygenase-2 (COX-2) inhibitors. These belong to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs):

- Etoricoxib helps to reduce the pain and swelling (inflammation) in the joints and muscles of people 16 years of age and older with osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and gout
- Etoricoxib is also used for the short term treatment of moderate pain after dental surgery in people 16 years of age and older.

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.

2. What you need to know before you take Etoricoxib

Do not take Etoricoxib:

- if you are allergic to etoricoxib or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including acetylsalicylic acid (aspirin) or COX-2 inhibitors (see section 4)
- if as a result of taking acetylsalicylic acid or any other NSAIDs you have experienced wheezing, chest tightness or breathlessness, a runny or blocked nose with pain in the face, swellings inside the nose causing blockages (nose polyps), or an allergic reaction such as an itchy skin rash known as hives (urticaria) or swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- if you currently have a stomach ulcer or bleeding in your stomach or intestines
- if you have serious problems with your liver or kidneys
- if you are pregnant or think you could be pregnant or are breast-feeding (see 'Pregnancy, breast-feeding and fertility')
- if you are under 16 years of age
- if you have inflammatory bowel disease, such as Crohn's disease, ulcerative colitis, or colitis
- if you have high blood pressure, persistently over 140/90 mmHg, that is not being controlled by treatment (check with your doctor or nurse if you are not sure whether your blood pressure is adequately controlled)
- if you have been told by your doctor that you have heart problems such as 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 (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 think any of these are relevant to you, do not take the tablets until you have consulted your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Etoricoxib if:

- you have a history of bleeding or ulcers in your stomach or intestines
- you are taking acetylsalicylic acid (even at low dose for heart protective purposes) or other NSAIDs
- 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 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 other problems with your heart, liver or kidneys
- you are being treated for an infection. Etoricoxib can mask or hide a fever, which is a sign of infection
- you use medicines to reduce blood clotting (e.g. warfarin)
- 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 Etoricoxib** to see if this medicine is suitable for you.

During treatment

In the first month of treatment you are at a higher risk of having serious skin reactions. Stop taking Etoricoxib if you get a skin rash, mouth lesions (damage to the skin or gums) or any other signs of an allergic reaction (see section 4 - Possible side effects).

If you get signs of problems with your liver such as a yellowing of the skin or whites of the eyes, dark urine, pale stools and generally feeling unwell, stop taking Etoricoxib and talk to your doctor.

Children and adolescents

Do not give this medicine to children and adolescents under 16 years of age.

Other medicines and Etoricoxib

Tell your doctor or pharmacist if you are taking, have recently taken or might take any 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:

- medicines that thin your blood (anticoagulants), such as warfarin
- rifampicin (an antibiotic)
- methotrexate (a drug used for suppressing the immune system, and often used in rheumatoid arthritis)
- ciclosporin or tacrolimus (medicines used for suppressing the immune system)
- lithium (a medicine used to treat some types of depression)
- 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
- 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)
- birth control pills (the combination may increase your risk of side effects)
- hormone replacement therapy (the combination may increase your risk of side effects)
- acetylsalicylic acid (aspirin) or other NSAIDs, the risk of stomach ulcers is greater if you take etoricoxib with these medicines
 - etoricoxib can be taken with low-dose aspirin, used for prevention of heart attacks or stroke. 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 doses of aspirin or other anti-inflammatory medicines while taking etoricoxib.

Etoricoxib with food

Etoricoxib may act quicker when taken without food. This should be considered when fast relief from pain or swelling is needed.

Pregnancy, breast-feeding and fertility

Etoricoxib must not be taken during pregnancy. If you are pregnant, think you may be pregnant or are planning to have a baby, do not take the tablets. If you become pregnant, stop taking the tablets and talk to your doctor. Ask your doctor or pharmacist for advice before taking this medicine.

It is not known if etoricoxib passes into human milk. If you are breast-feeding, or planning to breast-feed, talk to your doctor before taking this medicine. If you are taking Etoricoxib, you must not breast-feed.

Etoricoxib is not recommended in women attempting to become pregnant.

Driving and using machines

Dizziness, vertigo (sensation of spinning while remaining still) and sleepiness have been reported in some patients taking etoricoxib.

Do not drive or use any tools or machines if you experience these side effects.

Etoricoxib contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Etoricoxib

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Do not take more than the recommended daily dose for your condition. Your doctor will want to discuss your treatment from time to time. It is important that you use the lowest daily dose that controls your pain and you should not take Etoricoxib for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.

Take Etoricoxib by mouth once a day. This medicine can be taken with or without food.

Etoricoxib may act quicker when taken without food. Take this medicine without food if you need fast relief from the pain or swelling.

The recommended dose is:

Osteoarthritis

The recommended dose is 30 mg (equivalent to one 30 mg tablet) once a day, increase to a maximum of 60 mg (equivalent to two 30 mg tablets or equivalent to one 60 mg tablet) once a day if needed.

Rheumatoid arthritis

The recommended dose is 60 mg (equivalent to two tablets of 30 mg) once a day, increased to a maximum of 90 mg once a day if needed.

Ankylosing spondylitis

The recommended dose is 60 mg (equivalent to two tablets of 30 mg) once a day, increased to a maximum of 90 mg if needed.

Acute pain conditions

Etoricoxib should be used only for the period of time you have pain.

Gout

The recommended dose is 120 mg (equivalent to four 30 mg tablets, equivalent to two 60 mg tablets or equivalent to one 120 mg tablet) once a day (maximum daily dose) which should only be used for the acute painful period, limited to a maximum of 8 days treatment.

Pain following dental surgery

The recommended dose is 90 mg (equivalent to three tablets of 30 mg or equivalent to one 90 mg tablet) once daily (maximum daily dose), limited to a maximum of 3 days treatment. Talk to your doctor if you still have pain after taking Etoricoxib.

People with liver problems:

- If you have mild liver disease, you should not take more than 60 mg (equivalent to two 30 mg tablets, equivalent to one 60 mg tablet) a day
- If you have **moderate** liver disease, you should not take more than **30 mg a day**.

Use in children and adolescents

Etoricoxib should not be taken by children or adolescents under 16 years of age.

If you take more Etoricoxib than you should

You should never take more tablets than the doctor recommends. You may have problems with your stomach or intestines, heart or kidneys. If you do take too many Etoricoxib tablets, you should immediately talk to your doctor or go to the nearest hospital emergency department, taking the pack with you.

If you forget to take Etoricoxib

It is important to take Etoricoxib 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 a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you develop any of these signs you should stop taking Etoricoxib and immediately talk to your doctor or go to your nearest hospital emergency department (see also section 2, ‘What you need to know before you take Etoricoxib’):

- an allergic reaction such as a rash, hives, itching or swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing or swallowing
- shortness of breath, severe chest pains, severe headaches with increasing confusion or blurred vision with ankle swelling. These may be signs you have dangerously high blood pressure
- yellowing of the skin and eyes, dark urine, tiredness, fever, feeling sick (nausea), weakness, drowsiness and stomach pain. These may be signs of serious liver problems
- severe or continual stomach pain, black tar-like stools or bloodstained stool, being sick (vomiting) which may contain blood, bloated stomach, loss of appetite or feeling sick (nausea). These may be signs of serious problems with your stomach, intestine or pancreas
- a serious skin condition with severe blisters and bleeding in the lips, eyes, mouth and nose (Stevens-Johnson syndrome) or severe skin reactions which starts as painful red areas then large blisters and ends with peeling of layers of skin. This may be accompanied by fever and chills, aching muscles and generally feeling unwell (toxic epidermal necrolysis)
- an increase in the number of infections which you may see as fevers, severe chills, sore throat or mouth ulcers. These may indicate you have a low number of white blood cells
- an abnormally or dangerously fast heart beat
- sudden collapse, numbness or weakness in the arms or legs, headache, dizziness and confusion, disturbances in vision, difficulty swallowing, slurred, mixed up or loss of speech. These may be signs of a stroke or mini stroke caused by a clot or bleed affecting blood supply to part of the brain
- heavy or pressing sensation on your chest with chest pain and shortness of breath on exercise (these may be signs you have angina)
- sudden chest pain which may spread to the neck or arm, with a shortness of breath and clammy feeling. These may be signs of a heart attack or other problems with your heart
- a reduction in the working of the heart, which may cause tiredness, weakness and/or fluid retention such as swelling of the legs and ankles, difficulty breathing including coughing up frothy or watery phlegm
- producing little or no urine, cloudy urine or blood in the urine, pain when passing urine or lower back pain. These may be signs of serious problems with your kidneys.

Other possible side effects include:

Very common (may affect more than 1 in 10 people):

- stomach pain

Common (may affect up to 1 in 10 people):

- dry socket (inflammation and pain after tooth extraction)
- swelling of the legs and/or feet due to fluid retention (oedema)
- dizziness, headache
- fast or irregular heartbeat (palpitations), irregular heart rhythm (arrhythmia)
- increased blood pressure (hypertension)
- constipation, wind (excessive gas), gastritis (inflammation of the lining of the stomach), heartburn, diarrhoea, indigestion (dyspepsia)/stomach discomfort, feeling sick (nausea), being sick (vomiting), inflammation of the food pipe
- changes in blood tests related to your liver
- bruising
- weakness and tiredness, flu-like illness

Uncommon (may affect up to 1 in 100 people):

- chest or throat infection
- discomfort or a burning pain when passing water. This may be a sign you have a urinary tract infection
- tiredness, shortness of breath, coldness in your hands and feet and pale skin. These may be signs of a low number of red blood cells
- unexplained bruising or bleeding more frequently or for longer than normal. These may be signs of a low number of platelets
- appetite increases or decreases, weight gain
- anxiety, depression, decreases in mental sharpness; seeing, feeling or hearing things that are not there (hallucinations)
- changes in taste, inability to sleep, numbness or tingling of the hands or feet, reduced skin sensitivity, sleepiness
- blurred vision, eye irritation and redness
- ringing in the ears, vertigo (sensation of spinning while remaining still)
- changes in the electrical activity of the heart
- flushing, inflammation of the blood vessels
- cough, nose bleed
- changes in your bowel habits, dry mouth, irritable bowel syndrome
- muscle cramp or spasm, muscle pain or stiffness
- high levels of potassium in your blood, changes in blood or urine tests relating to your kidney

Rare (may affect up to 1 in 1,000 people):

- confusion, restlessness
- low blood levels of sodium

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. You can also report side effects directly via HPRAs Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Etoricoxib

Keep this medicine out of the sight and reach of children.

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

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

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.

6. Contents of the pack and other information

What Etoricoxib contains:

The active substance is etoricoxib. Each film-coated tablet contains 30, 60, 90 or 120 mg of etoricoxib.

The other ingredients are:

Core:

Anhydrous calcium hydrogen phosphate, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate.

Coating:

30 mg: Hypromellose, lactose monohydrate, titanium dioxide (E171), triacetin, carnauba wax, Brilliant blue FCF (E133), iron oxide black (E172), iron oxide yellow (E172).

60 mg: Hypromellose, lactose monohydrate, titanium dioxide (E171), triacetin, iron oxide yellow (E172), Indigo carmine (E132), carnauba wax.

90 mg: Hypromellose, lactose monohydrate, titanium dioxide (E171), triacetin, carnauba wax.

120 mg: Hypromellose, lactose monohydrate, titanium dioxide (E171), triacetin, Indigo carmine (E132), iron oxide yellow (E172), carnauba wax.

What Etoricoxib looks like and contents of the pack

30 mg Tablets: Blue green, film-coated, round tablet with 'E' on one side and '30' on the other side.

60 mg Tablets: Green, film-coated, round tablet with 'E' on one side and '60' on the other side.

90 mg Tablets: White, film-coated, round tablet with 'E' on one side and '90' on the other side.

120 mg Tablets: Pale green, film-coated, round tablet with 'E' on one side and '120' on the other side.

Pack sizes:

30 mg: Blister strips containing 2, 5, 7, 14, 20, 28, 49, 98 tablets; unit dose containing 28 or Calendar blister containing 28 tablets.

60 mg: Blister strips containing 2, 5, 7, 10, 14, 20, 28, 30, 49, 50, 84, 98, 100 tablets; unit dose containing 5, 28, 50, 100 or Calendar blister containing 28 tablets.

90 mg: Blister strips containing 2, 5, 7, 10, 14, 20, 28, 30, 49, 50, 84, 98, 100 tablets; unit dose containing 5, 7, 28, 50, 100 or Calendar blister containing 28 tablets.

120 mg: Blister strips containing 2, 5, 7, 10, 14, 20, 28, 30, 49, 50, 84, 98, 100 tablets; unit dose containing 5, 7, 28, 50, 100 or Calendar blister containing 28 tablets.

All strengths: Plastic bottles with screw cap containing 28, 100 or 500 tablets. The 500 tablets pack size is available for hospital use only.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Limited trading as Gerard Laboratories, 35/36 Baldoye Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturer

Mylan Hungary Kft, Mylan utca 1, Komarom, H-2900 Hungary.

Generics [UK] Ltd, Station close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

McDermott Laboratories Limited trading as Gerard Laboratories, 35/36 Baldoye Industrial Estate, Grange Road, Dublin 13, Ireland.

This medicinal product is authorised in the Member States of the EEA and in the United Kingdom (Northern Ireland) under the following names:

Germany	Etoricoxib Mylan 30 mg, 60 mg, 90 mg, 120 mg Filmtabletten
Finland	Etoricoxib Mylan 30 mg, 60 mg, 90 mg, 120 mg tabletti, kalvopäällysteinen
France	Etoricoxib Viatris 30 mg, 60 mg comprimé pelliculé
Ireland	Etoricoxib 30 mg, 60 mg, 90 mg, 120 mg film-coated tablets
The Netherlands	Etoricoxib Mylan 30 mg, 60 mg, 90 mg, 120 mg filmomhulde tabletten
Portugal	Etoricoxib Mylan 30 mg, 60 mg, 90 mg, 120 mg comprimidos revestidos por película
Spain	Etoricoxib Viatris 30 mg, 60 mg, 90 mg, 120 mg comprimidos recubiertos con película EFG
United Kingdom (Northern Ireland)	Etoricoxib Mylan 30 mg, 60 mg, 90 mg, 120 mg film-coated tablets

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