

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

Etoricoxib is indicated in adults and adolescents over 16 years of age.

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 (hypersensitive) 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 aspirin and COX-2 inhibitors (see Possible side effects, section 4).
- 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 (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 your doctor has diagnosed heart problems including heart failure (moderate or severe types), angina (chest pain)
- if you have had a heart attack, bypass surgery, peripheral arterial disease (poor circulation in legs or feet due to narrowed or blocked arteries),
- if you have had 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Etoricoxib:

- if you have a history of stomach bleeding or ulcers.
- if you are dehydrated, for example by a prolonged bout of vomiting or diarrhoea.
- if you have swelling due to fluid retention.
- if you have a history of heart failure, or any other form of heart disease.
- if 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.
- if you have any history of liver or kidney disease.
- if you are being treated for an infection. Etoricoxib can mask or hide a fever, which is a sign of infection.
- if you are a woman trying to become pregnant.
- if you are elderly (i.e. over 65 years of age).
- if 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 applies to you, **talk to your doctor before taking Etoricoxib** to see if this medicine is suitable for you.

Etoricoxib works equally well in older and younger adult 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 elderly patients.

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, including medicines obtained without a prescription.

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)
- 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)
- ciclosporin or tacrolimus (drugs used for suppressing the immune system)
- 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)
- aspirin, the risk of stomach ulcers is greater if you take Etoricoxib with aspirin
 - Aspirin for the prevention of myocardial infarction or cerebral infarction:
Etoricoxib 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
 - Aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs):
do not take **high dose** aspirin or other anti-inflammatory medicines while taking Etoricoxib

Etoricoxib with food and drink

The onset of the effect of Etoricoxib may be faster when taken without food.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Etoricoxib tablets must not be taken during pregnancy. If you are pregnant, 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.

Breast-feeding

It is not known if Etoricoxib is excreted in human milk. If you are breast-feeding, or planning to breast-feed, consult your doctor before taking Etoricoxib. If you are using Etoricoxib, you must not breast-feed.

Fertility

Etoricoxib is not recommended in women attempting to become pregnant.

Driving and using machines

Dizziness and sleepiness have been reported in some patients taking Etoricoxib.

Do not drive if you experience dizziness or sleepiness.

Do not use any tools or machines if you experience dizziness or sleepiness.

Etoricoxib contains lactose

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

Etoricoxib contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, 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 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 for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.

There are different strengths available for this medicine, and depending on your condition, your doctor will prescribe the tablet in the strength that is right for you.

The recommended dose is:

Osteoarthritis:

The recommended dose is 30 mg once a day, increase to a maximum of 60 mg (equivalent to 2 Etoricoxib 30 mg tablets) once a day if needed.

Rheumatoid arthritis:

The recommended dose is 60 mg once a day, increase to a maximum of 90 mg (equivalent to 3 Etoricoxib 30 mg tablets) once a day if needed.

Ankylosing spondylitis:

The recommended dose is 60 mg once a day, increase to a maximum of 90 mg once a day.

Acute pain conditions:

Etoricoxib should be used only for the acute painful period.

Gout:

The recommended dose is 120 mg (equivalent to 4 Etoricoxib 30 mg tablets) once a day which should only be used for the acute painful period, limited to a maximum of 8 days treatment.

Postoperative dental surgery pain:

The recommended dose is 90 mg once daily, limited to a maximum of 3 days treatment.

Osteoarthritis:

The recommended dose is 30 mg once a day (not realisable with the 60 mg strength), increase to a maximum of 60 mg once a day if needed.

Rheumatoid arthritis:

The recommended dose is 60 mg once a day, increase to a maximum 90 mg once a day if needed. This dosage is not realisable with 60 mg strength. For the treatment of rheumatoid arthritis another strength (Etoricoxib 90 mg) is available, please consult your doctor.

Ankylosing spondylitis:

The recommended dose is 60 mg once a day, increase to a maximum 90 mg once a day if needed. For the treatment of ankylosing spondylitis another strength (Etoricoxib 90 mg) is available, please consult your doctor.

Acute pain conditions:

Etoricoxib should be used only for the acute painful period.

Gout

The recommended dose is 120 mg (equivalent to 2 Etoricoxib 60 mg tablets) once a day which should only be used for the acute painful period, limited to a maximum of 8 days treatment.

Postoperative dental surgery pain

The recommended dose is 90 mg once daily, limited to a maximum of 3 days treatment. For the treatment of postoperative dental surgery pain another strength (Etoricoxib 90 mg) is available, please consult your doctor.

Osteoarthritis:

The recommended dose is 30 mg once a day, increase to a maximum of 60 mg once a day if needed. This dosage is not realisable with Etoricoxib 90 mg. For the treatment of osteoarthritis another strength (Etoricoxib 30 mg) is available, please consult your doctor.

Rheumatoid arthritis:

The recommended dose is 60 mg once a day, this dosage is not realisable with Etoricoxib 90 mg. increase to maximum of 90 mg once a day.

Ankylosing spondylitis:

The recommended dose is 60 mg once a day, this dosage is not realisable with Etoricoxib 90 mg. increase to maximum of 90 mg once a day.

Acute pain conditions:

Etoricoxib should be used only for the acute painful period.

Gout

The recommended dose is 120 mg once a day which should only be used for the acute painful period, limited to a maximum of 8 days treatment. This dosage is not realisable with Etoricoxib 90 mg. For the treatment of gout another strength (Etoricoxib 120 mg) is available, please consult your doctor.

Postoperative dental surgery pain

The recommended dose is 90 mg once daily, limited to a maximum of 3 days treatment.

Osteoarthritis:

The recommended dose is 30 mg once a day, increase to a maximum of 60 mg once a day if needed. This dosage is not realisable with Etoricoxib 120 mg. For the treatment of osteoarthritis another strength (Etoricoxib 30 mg) is available, please consult your doctor.

Rheumatoid arthritis:

The recommended dose is 60 mg once a day, increase to a maximum of 90 mg once a day if needed. This dosage is not realisable with Etoricoxib 120 mg. For the treatment of rheumatoid arthritis another strength (Etoricoxib 60 mg) is available, please consult your doctor

Ankylosing spondylitis:

The recommended dose is 60 mg once a day, increase to a maximum of 90 mg once a day if needed. This dosage is not realisable with Etoricoxib 120 mg. For the treatment of ankylosing spondylitis another strength (Etoricoxib 60 mg) is available, please consult your doctor.

Acute pain conditions:

Etoricoxib should be used only for the acute painful period.

Gout

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

Postoperative dental surgery pain

The recommended dose is 90 mg once daily, limited to a maximum of 3 days treatment. This dosage is not realisable with Etoricoxib 120 mg. For the treatment of postoperative dental surgery pain another strength (Etoricoxib 90 mg) is available, please consult your doctor.

People with liver problems

- If you have mild liver disease, you should not take more than 60 mg 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.

Patients older than 65 years No dose adjustment is necessary for elderly patients. As with other medicines, caution should be exercised in elderly patients.

Method of administration

Etoricoxib is for oral use. Take the tablets once a day. Etoricoxib can be taken with or without food.

If you take more Etoricoxib than you should

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

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 the forgotten tablet.

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 talk to your doctor immediately (see section 2. What you need to know before you take Etoricoxib:

- 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

The following side effects can occur during treatment with Etoricoxib:

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

- stomach pain

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

- alveolar osteitis (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
- bruises
- weakness and fatigue, flu-like illness

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

- gastroenteritis (inflammation of the gastrointestinal tract that involves both the stomach and small intestine/stomach flu), upper respiratory infection, urinary tract infection
- changes in laboratory results (decreased number of red blood cells, decreased number of white blood cells, platelets decreased)
- hypersensitivity (an allergic reaction including hives which may be serious enough to require immediate medical attention)
- appetite increases or decreases, weight gain

- anxiety, depression, decreases in mental sharpness; seeing, feeling or hearing things that are not there (hallucinations)
- taste alteration, inability to sleep, numbness or tingling, sleepiness
- blurred vision, eye irritation and redness
- ringing in the ears, vertigo (sensation of spinning while remaining still)
- abnormal heart rhythm (atrial fibrillation), fast heart rate, heart failure, feeling of tightness, pressure or heaviness in the chest (angina pectoris), heart attack
- flushing, stroke, mini-stroke (transient ischaemic attack), severe increase in blood pressure, inflammation of the blood vessels
- cough, breathlessness, nose bleed
- stomach or bowel bloating, changes in your bowel habits, dry mouth, stomach ulcer, inflammation of the stomach lining that can become serious and may lead to bleeding, irritable bowel syndrome, inflammation of the pancreas
- swelling of the face, skin rash or itchy skin, redness of the skin
- muscle cramp/spasm, muscle pain/stiffness
- high levels of potassium in your blood, changes in blood or urine tests relating to your kidney, serious kidney problems
- chest pain

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

- angioedema (an allergic reaction with swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing, which may be serious enough to require immediate medical attention)/anaphylactic/anaphylactoid reactions including shock (a serious allergic reaction that requires immediate medical attention)
- confusion, restlessness
- liver problems (hepatitis)
- low blood levels of sodium
- liver failure, yellowing of the skin and/or eyes (jaundice)
- severe skin reactions

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 HPRC 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 Etoricoxib after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store in the original package 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** milligrams of etoricoxib.

- The other ingredients (excipients) are: Core: calcium hydrogen phosphate, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, lactose monohydrate and hydroxypropyl cellulose. Tablet coating: lactose monohydrate, hypromellose, titanium dioxide (E171), triacetin. The 30 mg, 60 mg and 120 mg tablets also contain yellow iron oxide (E172, colouring agent) and indigo carmine lake (E132, colouring agent).

What Etoricoxib looks like and contents of the pack

Etoricoxib film-coated tablets are available in four strengths:

- **30 mg:** Blue-green, apple-shaped, biconvex film coated tablets engraved ‘30’ on one face and other face plain. The 30 mg strength is available in blister packs containing 7, 10, 20, 28, 50 and 98 tablets.
- **60 mg:** Dark-green, apple-shaped, biconvex film coated tablets engraved ‘60’ on one face and other face plain. The 60 mg strength is available in blister packs containing 7, 10, 14, 20, 28, 50 and 100 tablets.
- **90 mg:** White, apple-shaped, biconvex film coated tablets engraved ‘90’ on one face and other face plain. The 90 mg strength is available in blister packs containing 7, 10, 14, 20, 28, 30, 50 and 100 tablets.
- **120 mg:** Pale-green, apple-shaped, biconvex film coated tablets engraved ‘120’ on one face and other face plain. The 120 mg strength is available in blister packs containing 5, 7, 10, 14, 20, 28, 30, 50 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Chanelle Medical Unlimited Company, Loughrea, Co. Galway, Ireland.

Manufacturers

Chanelle Medical Unlimited Company,
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This medicinal product is authorised in the Member States of the EEA under the following names:

Germany: Etoricoxib Micro labs 30mg, 60mg, 90mg & 120mg Filmtabletten

Ireland: Etoricoxib 30mg, 60mg, 90mg & 120mg Film-coated Tablets

Malta: Leidcox 30mg, 60mg, 90mg & 120mg film-coated Tablets

Portugal: Etoricoxib Azevedos

Spain: Etoricoxib Kern Pharma 30mg, 60mg, 90mg & 120mg comprimidos EFG

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