Package leaflet: Information for the patient

Etoricoxib Krka 30 mg film-coated tablets
Etoricoxib Krka 60 mg film-coated tablets
Etoricoxib Krka 90 mg film-coated tablets
Etoricoxib Krka 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 Krka is and what it is used for

What is Etoricoxib Krka
- Etoricoxib Krka contains the active substance etoricoxib. Etoricoxib Krka 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).

What is Etoricoxib Krka used for?
- Etoricoxib Krka 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 Krka 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 Krka

Do not take Etoricoxib Krka:
- 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 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 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 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 narrow 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 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 Krka if:
- You have a history of stomach bleeding or ulcers.
- 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 heart failure, or any other form of heart disease.
- You have a history of high blood pressure. Etoricoxib Krka 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 history of liver or kidney disease.
- You are being treated for an infection. Etoricoxib Krka can mask or hide a fever, which is a sign of infection.
- You have diabetes, high cholesterol, or are a smoker. These can increase your risk of heart disease.
- You are a woman trying to become pregnant.
- You are over 65 years of age.

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

Etoricoxib Krka works equally well in older and younger adult patients. If you are over 65 years of age, your doctor will want to appropriately keep a check on you. No dosage adjustment is necessary for patients over 65 years of age.

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

Other medicines and Etoricoxib Krka
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 Krka:

- 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 (drugs 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, the risk of stomach ulcers is greater if you take Etoricoxib Krka with acetylsalicylic acid.
  - Acetylsalicylic acid for prevention of heart attacks or stroke:
  Etoricoxib Krka can be taken with low-dose acetylsalicylic acid. If you are currently taking low dose acetylsalicylic acid to prevent heart attacks or stroke, you should not stop taking acetylsalicylic acid until you talk to your doctor.
  - Acetylsalicylic acid and other non-steroidal anti-inflammatory drugs (NSAIDs):
  do not take **high dose** acetylsalicylic acid or other anti-inflammatory medicines while taking Etoricoxib Krka.

Etoricoxib Krka with food and drink
The onset of the effect of Etoricoxib Krka may be faster when taken without food.

Pregnancy, breast-feeding and fertility

Pregnancy

Etoricoxib Krka tablets 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.

Breast-feeding

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

Fertility

Etoricoxib Krka is not recommended in women attempting to become pregnant.

Driving and using machines
Dizziness and sleepiness have been reported in some patients taking Etoricoxib Krka.
Do not drive if you experience dizziness or sleepiness.

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

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

3. How to take Etoricoxib Krka

Always take this medicine exactly as your doctor has told you. You should 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 Krka 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 medicinal product and depending on your disease your doctor will prescribe the tablet strength that is appropriate for you.

The recommended dose is:

Osteoarthritis
The recommended dose is 30 mg once a day, increase to a maximum of 60 mg once a day if needed.

Rheumatoid arthritis
The recommended dose is 60 mg etoricoxib once a day. The dose can be increased to a maximum of 90 mg.

Ankylosing spondylitis
The recommended dose is 60 mg etoricoxib once a day. The dose can be increased to a maximum of 90 mg once a day if needed.

Treatment of acute pain
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.

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

Elderly
No dose adjustment is necessary for elderly patients. As with other medicines, caution should be exercised in elderly patients.

Method of administration

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

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

If you forget to take Etoricoxib Krka
It is important to take Etoricoxib Krka 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 Etoricoxib Krka and talk to your doctor immediately (see What you need to know before you take Etoricoxib Krka section 2):
- 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

Other side effects that may occur during treatment with Etoricoxib Krka:

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 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

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 values (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 HPRA 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 Krka

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 packaging after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Krka contains
- The active substance is etoricoxib.
  Each film-coated tablet contains 30 mg, 60 mg, 90 mg or 120 mg etoricoxib.
- The other ingredients are: microcrystalline cellulose, calcium hydrogen phosphate, croscarmellose sodium, sodium stearyl fumarate, colloidal anhydrous silica in the tablet core and poly(vinyl alcohol), titanium dioxide (E171), macrogol 3000, talc, yellow iron oxide E172 (*in Etoricoxib Krka 60 mg film-coat tablets*) and red iron oxide E172 (*in Etoricoxib Krka 90 mg and 120 mg film-coat tablets*) in film coating. See section 2 “Etoricoxib Krka contains sodium”.

What Etoricoxib Krka looks like and contents of the pack

Etoricoxib Krka film-coated tablets are available in four strenghts:
Etoricoxib Krka 30 mg film-coated tablets are white or almost white, round (diameter: 6 mm), slightly biconvex, film coated tablets with beveled edges.
Etoricoxib Krka 60 mg film-coated tablets are slightly brownish yellow, round (diameter: 8 mm), biconvex, film coated tablets with beveled edges, engraved with mark “60” on one side of the tablet.
Etoricoxib Krka 90 mg film-coated tablets are pink, round (diameter: 9 mm), biconvex, film coated tablets with beveled edges, engraved with mark “90” on one side of the tablet.
Etoricoxib Krka 120 mg film-coated tablets are brownish red, round (diameter: 10 mm), slightly biconvex, film coated tablets with beveled edges, scored on one side of the tablet. The score line is not intended for breaking the tablet.

Etoricoxib Krka 30 mg film-coated tablets
Boxes of 7, 14, 28, 30, 56, 60, 84, 98 or 100 tablets in blisters are available.
Etoricoxib Krka 60 mg film-coated tablets
Boxes of 7, 14, 20, 28, 30, 50, 56, 60, 84, 98 or 100 tablets in blisters are available.
Etoricoxib Krka 90 mg film-coated tablets
Boxes of 5, 7, 14, 20, 28, 30, 50, 56, 60, 84, 98 or 100 tablets in blisters are available.
Etoricoxib Krka 120 mg film-coated tablets
Boxes of 5, 7, 14, 20, 28, 30, 50, 56, 60, 84, 98 or 100 tablets in blisters are available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium, Denmark, Spain, Finland, Ireland, Iceland, Norway, Sweden	Etoricoxib Krka
Bulgaria, Czech Republic, Hungary, Poland, Romania, Slovenia, Slovakia	Roticox
Germany	Etoriax
Estonia, Croatia	Etoxib
Lithuania, Latvia	Bericox
Portugal	Etoricoxib TAD
United Kingdom (Northern Ireland)	Etoricoxib

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