



Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

Etoricoxib Dexcel 30, 60, 90, 120 mg, tablets

Each tablet contains 30, 60, 90, 120 mg of Etoricoxib respectively.

Inactive ingredients and allergens in the medicine - see section 6 "Additional Information" and in section 2 "Important Information about some of the ingredients of the medicine".

Read this entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to a doctor or pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

This medicine is not intended for children and adolescents under 16 years of age.

1. What is the medicine intended for?

Etoricoxib 30 mg helps to reduce the pain and swelling (inflammation) in the joints and muscles of people who suffer from osteoarthritis.

Etoricoxib 60 mg helps to reduce the pain and swelling (inflammation) in the joints and muscles of people who suffer from osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

Etoricoxib 90 mg helps to reduce the pain and swelling (inflammation) in the joints and muscles of people who suffer from rheumatoid arthritis and ankylosing spondylitis.

Etoricoxib 90 mg is also used for the short term treatment of moderate pain after dental surgery.

Etoricoxib 120 mg helps to reduce the pain and swelling (inflammation) in the joints and muscles of people who suffer from gout.

Therapeutic group: Etoricoxib Dexcel 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).

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 and recurring attacks of very painful inflammation and redness of the joints. It is caused by deposits of mineral crystals in the joints.

What is ankylosing spondylitis?

Ankylosing spondylitis is an inflammatory disease of the spine and large joints.

2. Before Using the Medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (etoricoxib) or any of the other ingredients this medicine contains (detailed in section 6)
- You are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors (see section 4 "Side effects")
- You have a current stomach ulcer or bleeding in your stomach or intestines
- You have serious liver disease
- You have serious kidney disease
- You are pregnant or could be pregnant or you are breastfeeding (see "Pregnancy, breastfeeding and fertility")
- You are under 16 years of age
- You have inflammatory bowel disease, such as Crohn's Disease, ulcerative colitis or colitis
- 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)
- You suffer from problems of the heart including heart failure (moderate or severe), angina (chest pain)
- You suffer from ischemic heart disease, have had a heart attack or bypass surgery or peripheral vascular disease (poor circulation in the legs or feet due to narrowing or blocked arteries)
- You have had any kind of stroke (including ministroke, transient ischemic attack or TIA). Etoricoxib may slightly increase the risk of heart attack and stroke and this is why it should not be used in patients 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.

Special warnings regarding the use of the medicine

Before treatment with **Etoricoxib Dexcel**, tell the doctor if:

- You have a history of stomach bleeding or ulcers.
- You are dehydrated, for example by a prolonged bout of vomiting or diarrhea.
- 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 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 can mask or hide a fever which is a sign of infection.
- You have diabetes, high cholesterol or if you are a smoker. These factors 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 Dexcel** to see if this medicine is suitable for you.

Etoricoxib 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 use the medicine in children and adolescents under 16 years of age.

Drug Interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Especially if you are taking any of the following medicines, your doctor may want to monitor you to check that your medicines are working properly, after starting treatment with

Etoricoxib Dexcel:

- medicines that thin your blood (anticoagulants), such as warfarin
- rifampicin (an antibiotic)
- methotrexate (a medicine used for suppressing the immune system and often used to treat 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 treat high blood pressure and heart failure, called ACE inhibitors and angiotensin receptor blockers, such as enalapril, ramipril, losartan, 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)
- aspirin, the risk of stomach ulcers is greater if you take etoricoxib with aspirin.
 - aspirin for prevention of heart attacks or stroke: etoricoxib can be taken with **low doses** of aspirin. If you are currently taking a low-dose aspirin to prevent heart attacks or stroke, you should not stop taking aspirin without consulting your doctor.
 - aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs):
Do not take a **high-dose** aspirin or other anti-inflammatory medicines while taking etoricoxib.

Use of this medicine and food

Etoricoxib Dexcel tablets may be taken with or without food. The onset of the effect of etoricoxib may be faster when taken without food.

Pregnancy, breastfeeding and fertility

Pregnancy

Etoricoxib Dexcel 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 them and consult your doctor. Consult a doctor if you are unsure or need further advice.

Breastfeeding

It is not known if etoricoxib is excreted in human milk. If you are breastfeeding or planning to breastfeed, consult your doctor before taking **Etoricoxib Dexcel**.

If you are using **Etoricoxib Dexcel**, you must not breastfeed.

Fertility

Etoricoxib Dexcel is not recommended for 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.

Important information about some of the ingredients of the medicine

Etoricoxib Dexcel contains lactose. If you have been told by your doctor that you have intolerance to certain types of sugar, consult a doctor before taking this medicine.

This medicine contains less than 1 mmol (23 mg) sodium per tablet, i.e., it is essentially "sodium free".

3. How should you use this medicine?

Always use this medicine according to the doctor's instructions. Check with a doctor or pharmacist if you are not sure about the dosage and the manner of treatment. The dosage and manner of treatment will be determined by the doctor only.

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 Dexcel** 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 disease your doctor will prescribe the strength that is appropriate for you.

The usual recommended dosage is:

Osteoarthritis: the recommended dose is 30 mg once a day, may be increased to a maximum of 60 mg once a day if needed.

Rheumatoid arthritis: the recommended dose is 60 mg once a day, may be increased to a maximum of 90 mg once a day if needed.

Ankylosing spondylitis: the recommended dose is 60 mg once a day, may be increased to a maximum of 90 mg once a day if needed.

For acute gouty arthritis and postoperative dental surgery pain, etoricoxib should only be used for the symptomatic pain 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 a day, limited to a maximum of 3 days treatment.

Patients with liver problems

- If you have mild liver disease, you should not take more than 60 mg once a day.
- If you have **moderate** liver disease, you should not take more than 30 mg a day.

Do not exceed the recommended dose.

Use in children and adolescents

Etoricoxib Dexcel should not be given to children or adolescents under 16 years of age.

Elderly

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

Method of administration

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

Swallow the medicine with a small amount of water.

Do not halve the tablets since there is no score line. No information is available with regards to crushing/chewing the tablets.

If you have accidentally taken a higher dosage

You should never take more tablets than the doctor recommended. If you have taken too many **Etoricoxib Dexcel** tablets, you should seek medical attention immediately.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

It is important to take **Etoricoxib Dexcel** as your doctor has prescribed. If you forgot to take this medicine at the designated time, do not take a double dose. Take the next dose at the regular time the following day and consult a doctor. Medical treatment should be maintained as recommended by the doctor.

Even if there is an improvement in your health, do not stop taking this medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

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

4. Side effects

Like any medicine, use of **Etoricoxib Dexcel** may cause side effects in some users. Do not be alarmed by reading the list of side effects, you may not suffer from any of them.

If you develop any of these signs you should stop taking Etoricoxib Dexcel and refer to a doctor immediately (see "Before using the medicine", section 2):

- shortness of breath, chest pains or ankle swelling appear or worsen
- yellowing of the skin and eyes (jaundice) - these are signs of liver problems
- severe or continuous stomach pain or black stool
- an allergic reaction - which can include skin reactions such as ulcers, or blistering, or swelling of the face, lips, tongue or throat which may cause difficulty in breathing.

Very Common side effects (effects that appear in more than 1 in 10 users):

- stomach pain

Common side effects (effects that appear in 1-10 out of 100 users):

- dry socket (inflammation and pain after a tooth extraction)
- swelling of the legs and/or feet due to fluid retention (edema)
- dizziness, headache
- palpitations (fast or irregular heartbeat), irregular heart rhythm (arrhythmia)
- increase in blood pressure
- wheezing or shortness of breath (bronchospasms)
- constipation, wind (excessive gas), gastritis (inflammation of the lining of the stomach), heartburn, diarrhea, indigestion (dyspepsia)/stomach discomfort, nausea, being sick (vomiting), inflammation of the esophagus, mouth ulcers
- changes in blood tests related to liver
- bruising
- weakness and fatigue, flu-like illness

Uncommon side effects (effect that appear in 1-10 out of 1,000 users):

- 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, decreased platelets)

- hypersensitivity (an allergic reaction including hives which may be serious enough to require immediate medical attention)
- appetite increases or decreases, weight gain
- anxiety, depression, dulling of senses; seeing, feeling or hearing things that are not there (hallucinations)
- taste alterations, 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 (TIA - transient ischemic attack), severe increase in blood pressure, inflammation of the blood vessels
- cough, breathlessness, nose bleed
- gastric 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 kidneys, serious kidney problems
- chest pain

Rare side effects (effects that appear in 1-10 out of 10,000 users):

- angioedema (an allergic reaction with swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing and 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

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health that "טיפול עקב לזואי תופעות על דיווח" via the link can be found on the home page of the Ministry of Health website (www.health.gov.il), directing to the online form of adverse events reporting or via the following link: <http://sideeffects.health.gov.il>

5. How to store the medicine

- **Avoid Poisoning!** This medicine and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date stated on the package. The expiry date (תפוגה תאריך) refers to the last day of that month.
- **Storage conditions:** store below 25°C.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. Additional Information

In addition to the active ingredient, the medicine also contains:

Lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, hypromellose (E464), magnesium stearate, titanium dioxide (E171), triacetin (E1518), carnauba wax.

Etoricoxib Dexcel 30, 60 and 120 mg tablets also contain: Lake brilliant blue (E133), Lake quinoline yellow (E104)

Etoricoxib Dexcel 60 and 120 mg tablets also contain: Iron oxide yellow (E172)

What the medicine looks like and contents of the package

Etoricoxib Dexcel 30 mg: round blue-green colored tablets. 28 tablets per package.

Etoricoxib Dexcel 60 mg: round dark green colored tablets. 14 tablets per package.

Etoricoxib Dexcel 90 mg: round white colored tablets. 14 tablets per package.

Etoricoxib Dexcel 120 mg: round light green colored tablets. 7 tablets per package.

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Drug registration number at the national drug registry of the Ministry of Health:

Etoricoxib Dexcel 30 mg: 160-15-34747-00

Etoricoxib Dexcel 60 mg: 160-16-34749-00

Etoricoxib Dexcel 90 mg: 160-17-34750-00

Etoricoxib Dexcel 120 mg: 160-18-34751-00

Manufacturer and registration holder:

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