

COX-OD 60, COX-OD 90 and COX-OD 120

Etoricoxib Film Coated Tablets (60mg, 90mg and 120mg)

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What is COX-OD used for

Your doctor has prescribed COX-OD tablet for:

- treatment of osteoarthritis
- treatment of rheumatoid arthritis
- treatment of ankylosing spondylitis
- treatment of acute pain after minor dental procedures
- treatment of menstrual pain
- treatment of gout

Osteoarthritis is a joint disease. It results from the gradual breakdown of the cartilage that cushions the ends of the bones, resulting in pain, inflammation, tenderness, stiffness, and physical disability.

Rheumatoid arthritis is a chronic disease that causes pain, stiffness, swelling and loss of functions in the joints and inflammation in other body organs.

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

Gout is a disorder characterized by sudden, recurring attacks of pain and inflammation in one or more joints.

You may obtain further information from your doctor or pharmacist, who have more detailed information.

How COX-OD works

COX-OD tablet is a member of a group of medicines called selective COX-2 inhibitors that are used to reduce pain and inflammation. COX-OD tablet is not a narcotic.

Before you use COX-OD

-When you must not use it

Do not take COX-OD tablet if you:

- are allergic to etoricoxib or any of other ingredients of this medicine.
- have had 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 has not been controlled by treatment
- are or could be pregnant

-Before you start to use it

Tell your doctor about any medical problems or allergies you have or have had, including:

- history of angina, heart attack or a blocked artery in your heart
- narrow or blocked arteries of the extremities
- kidney disease
- liver diseases
- dehydration, for example by a prolonged bout of vomiting or diarrhea
- have or had ulceration, bleeding or perforation of your stomach or intestines
- heart failure
- high blood pressure
- swelling due to fluid retention
- an allergic reaction to aspirin or other anti-inflammatory medicines (commonly known as NSAIDs)
- a history of stroke or mini stroke
- conditions which increase your risk of coronary artery disease or atherosclerosis such as high blood pressure, diabetes, high cholesterol or smoking.
- being treated for an infection. COX-OD tablet can mask or hide a fever, which is a sign of infection.
- have had asthma, nasal inflammation, and/or itching or hives caused by Aspirin or NSAIDs.
- suffering from dyspepsia (indigestion).

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.

Use in elderly

COX-OD tablet works equally well in older and younger adult patients. Adverse experiences may occur at a higher incidence in older patients compared to younger 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 older patients.

Use in pregnancy and breastfeeding

Tell your doctor if you are:

- COX-OD tablet may cause fetal harm and should not be used by a woman who is attempting to become pregnant or becomes pregnant during treatment.
- Breastfeeding or plan to breastfeed.

-Taking other medications

You should always tell your doctor about all medicines that you are taking to plan to take, including those obtained without a prescription.

Your doctor may want to check that your medicines are working properly if you are taking:

- warfarin (a blood thinner)
- rifampin (an antibiotic)
- diuretics (water tablets)
- ACE inhibitors and angiotensin receptor blockers (medicines used for high blood pressure and heart failure)
- lithium (a medicine used to treat a certain type of depression)
- birth control pills
- hormone replacement therapy
- methotrexate (a medicine used for suppressing the immune system)

COX-OD tablet can be taken with low-dose aspirin. If you are currently taking low-dose aspirin for prevention of heart attack or stroke, you should not discontinue without consulting your doctor because COX-OD tablet cannot substitute for aspirin for this purpose.

How to use COX-OD

-How much to use

COX-OD tablet should be taken once a day. You may take COX-OD tablet with

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or without food.

Your doctor will decide what dose of COX-OD tablet you should take and how long you should take.

For treatment of rheumatoid arthritis:

- The recommended dose is 60 mg once a day, and may increase to 90 mg once a day if needed

For treatment of ankylosing spondylitis:

- The recommended dose is 60 mg once a day, and may increase to 90 mg once a day if needed.

Acute pain conditions:

- The recommended dose is 90mg or 120mg once daily. COX-OD should be used only for the acute period limited to a maximum of 8 days.

For the relief of gout attacks and the treatment of menstrual pain:

- The recommended dose is 120 mg once a day which should only be used for the acute painful period.

For the relief of pain after minor dental procedures

- The recommended dose is 90 mg once a day.

Do not exceed the daily doses for each condition stated above.

If you have mild or moderate liver disease, your doctor might prescribe you a lower dose or recommend that you do not take COX-OD.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue taking COX-OD tablet as recommended by doctor or pharmacist.

-If you forget to use it

Try to take COX-OD tablet as prescribed. However, if you miss a dose, please do not take an extra dose. Just resume your usual schedule the following day.

-If you use too much (overdose)

If you take more than the prescribed dosage, contact your doctor immediately.

While you are using it

-Things you must do

Consult your doctor if:

- Any of the following symptoms appear or worsen: shortness of breath, chest pains or ankle swelling. Stop your treatment with COX-OD tablet and consult a doctor, as soon as is practical.
- You have kidney, liver or heart disease, your doctor will want to appropriately keep a check on you.
- You develop any symptoms that could indicate a severe allergic reaction such as inability to breathe or a serious skin reaction, you must consult a doctor on an urgent basis.

Your doctor will want to discuss your treatment from time to time. It is important that you use the lowest dose that control your pain.

COX-OD tablet can increase blood pressure in some people, especially in high doses, and this could increase the risk of heart attacks and strokes. Your doctor will want to check your blood pressure from time to time, in order to ensure that it is safe to continue the treatment.

-Things you must not do

Do not share COX-OD tablet with anyone else; it was prescribed only for you.

Do not take COX-OD tablet 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

Be careful driving or operating machinery until you know how COX-OD affects you.

COX-OD contains lactose. If you have been told by your doctor that you are unable to tolerate some sugars, contact your doctor before taking this medicinal product.

Side effects

Any medicine may have unintended or undesirable effects, so-called side effects. Like all prescription medicines, COX-OD tablet may cause side effects.

Some of the side effects are:-

- dizziness,
- swelling of the legs and/or feet,
- weakness and fatigue,
- high blood pressure,
- nausea,
- heartburn,
- upset stomach,
- headache,

Additionally, the following have been reported:

- allergic reactions (which may be serious enough to require immediate medical attention) including swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing, wheezing, rash, itching and hives;
- redness of the skin,
- severe skin reactions which may occur without warning,
- taste alteration,
- abnormal rhythm of the heart,
- heart failure,
- palpitations,
- feeling of tightness, pressure or heaviness in the chest,
- stomach pain,
- stomach ulcers that may become serious and may bleed and may occur at any time during use and without warning,
- vomiting,
- liver problem including liver failure, yellowing of the skin and eyes (jaundice)
- serious kidney problems
- high levels of potassium in your blood,
- insomnia
- anxiety
- depression
- restlessness
- drowsiness
- mouth ulcers
- diarrhea,
- severe increase in blood pressure,
- confusion,
- hallucinations,
- platelets decreased, blurred vision

Other side effects may also occur rarely, and as with any prescription medicine, some side effects may be serious. Ask your doctors or pharmacist for more information.

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Both have a more complete list of side effects. Tell your doctor or pharmacist promptly about these or any other unusual symptoms.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumer → Reporting → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI))

Storage and Disposal of COX-OD

-Storage

- Keep this medicine out of the sight and reach of children.
- Store below 30°C.
- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Blisters: Store in the original package in order to protect from moisture.

-Disposal

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.

Product Description

-What it looks like

60 mg tablet: Dark-green, apple-shaped, biconvex film coated tablets engraved '60' on one face and other face plain

90 mg tablet: White, apple-shaped, biconvex film coated tablets engraved '90' on one face and other face plain

120 mg tablet: Pale-green, apple-shaped, biconvex film coated tablets engraved '120' on one face and other face plain

-Ingredients

Active ingredient(s)
Etoricoxib

Inactive ingredient(s)

60 mg tablet:

Microcrystalline Cellulose, Phosphate
Crystalline Calcium Hydrogen Anhydrous, Lactose
Croscarmellose Sodium, Hydroxypropyl
Monohydrate, Magnesium Stearate,
Opadry II Green 32K510012

90 mg tablet:

Microcrystalline Cellulose, Phosphate
Crystalline Calcium Hydrogen Anhydrous, Lactose
Croscarmellose Sodium, Hydroxypropyl
Monohydrate, Magnesium Stearate,
Opadry II White 32K580000

120 mg tablet:

Microcrystalline Cellulose, Phosphate
Crystalline Calcium Hydrogen Anhydrous, Lactose
Croscarmellose Sodium, Hydroxypropyl
Monohydrate, Magnesium Stearate,
Opadry II Green 32K510013

-MAL number

COX-OD 60: MAL25056027AZ
COX-OD 90: MAL25056028AZ
COX-OD 120: MAL25056029AZ

Manufacturer

Micro Labs Limited,
Plot No. S.155 To S.159 & N1 Verna
Industrial Estate
Phase III & Phase IV Verna Salcette
Goa
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India

Product Registration Holder

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Malaysia.

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