

COXITOR 90MG & 120MG FILM-COATED TABLET

Etoricoxib 90mg & 120mg

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WHAT COXITOR IS USED FOR

Coxitor helps to reduce the pain and swelling (inflammation) in the joints and muscles of people with osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and gout.

Coxitor is also used for the short-term treatment of moderate pain after dental surgery.

HOW COXITOR WORKS

Coxitor 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).

BEFORE YOU USE COXITOR

When you must not use it

Do not take Coxitor:

- if you are allergic to etoricoxib or any of the other ingredients of this medicine (see section on ingredients)
- if you are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including acetylsalicylic acid and COX-2 inhibitors (see section on side effects)
- 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 pregnant or breast-feeding
- 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) 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 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 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.

Pregnancy, breast-feeding and fertility

- Pregnancy

Coxitor must not be taken during pregnancy. If you are pregnant or think you may be pregnant, or if you are planning to have a baby, do not take Coxitor. If you become pregnant, stop taking Coxitor 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 Coxitor. If you are using Coxitor, you must not breast-feed.

- Fertility

Etoricoxib may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems to become pregnant.

Driving and using machines

Dizziness and sleepiness have been reported in some patients taking Coxitor. Do not drive if you experience dizziness or sleepiness. Do not use any tools or machines if you experience dizziness or sleepiness.

Coxitor contains lactose

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

Before you start to use it

Talk to your doctor before taking Coxitor, if any of the following apply to you:

- 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 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 Coxitor to see if this medicine is suitable for you.

Coxitor 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.

Taking other medicines

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 Coxitor:

- medicines that thin your blood (anticoagulants), such as warfarin
- rifampicin (an antibiotic)
- methotrexate (a medicine 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)

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- ciclosporin or tacrolimus (medicine used for suppressing the immune system).
- digoxin (a medicine for heart failure and irregular heart rhythm).
- minoxidil (a medicine used to treat high blood pressure).
- salbutamol tablets or oral solution (a medicine for asthma).
- birth control pills.
- hormone replacement therapy.
- acetylsalicylic acid, the risk of stomach ulcers is greater if you take Coxitor with acetylsalicylic acid.
- Coxitor 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.
- do not take high dose acetylsalicylic acid or other anti-inflammatory medicines while taking Coxitor.

HOW TO USE COXITOR

How much to use

Osteoarthritis: The recommended dose is 30 mg once daily. Increased dose of 60 mg may increase effectiveness.

Rheumatoid Arthritis (RA): The recommended dose is 60 mg once a day, and may increase to 90 mg once a day if needed.

Primary dysmenorrhea: The recommended dose is 120mg once daily.

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

Acute Gouty Arthritis: The recommended dose is 120 mg once daily. Etoricoxib 120 mg should be used only for the acute symptomatic period, limited to a maximum of 8 days treatment.

Analgesia: Acute Pain and Minor Dental Procedures: The recommended dose is 90 mg once daily, limited to a maximum of 3 days treatment.

Doses greater than those recommended for each indication have either not demonstrated additional efficacy or have not been studied. Therefore, the dose for osteoarthritis (OA)

should not exceed 60 mg daily. The dose for RA should not exceed 90 mg daily. The dose for acute gout should not exceed 120 mg daily. The dose for postoperative acute dental surgery pain should not exceed 90 mg daily, maximum 3 days.

As the cardiovascular risks of selective COX-2 inhibitors may increase with dose and duration of exposure, the shortest duration possible and the lowest effective daily dose should be used. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically.

Use in children and adolescents

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

Elderly

No dose adjustment is necessary for elderly patients. Caution should be exercised in elderly patients.

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.

People with kidney problems

- If you have severe kidney disease (creatinine clearance <30ml/min), you should not take Coxitor.
- If you have lesser degree of kidney disease (creatinine clearance ≥30ml/min), no dosage adjustment is needed.

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 Coxitor for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.

When to use it

Coxitor is for oral use. Take the tablets once a day. Coxitor can be taken with or without food. The onset of the effect of Coxitor may be faster when taken without food.

How long to use it

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

If you forget to use it

It is important to take Coxitor 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 dose.

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

If you use too much (overdose)

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

There have been reports of acute overdose with etoricoxib, although adverse experiences were not reported in the majority of cases. The most frequently observed adverse experiences were consistent with the safety profile for etoricoxib (e.g. gastrointestinal events, cardio renal events).

WHILE YOU ARE USING IT

Things you must do

Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists that are treating you that you are taking Coxitor.

Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Coxitor to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Be careful when driving or using machinery until you know how this medicine affects you.

SIDE EFFECTS

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

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If you develop any of these signs stop Coxitor and talk to your doctor immediately:

- 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 Coxitor:

Very Common

- stomach pain

Common

- 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

- gastroenteritis (inflammation of the gastrointestinal tract that involves both the stomach and small intestine/ stomach flu), upper respiratory infection, urinary tract infection
- 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

- 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

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

STORAGE AND DISPOSAL OF COXITOR

Storage

- Do not store above 30°C.
 - 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 the month.

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

90 mg tablets - White round, biconvex, film-coated tablets.

120 mg tablets - Pale green, round, biconvex, film-coated tablets.

Ingredients

Active ingredient:

90 mg tablets - each film-coated tablet contains 90 mg of etoricoxib.

120 mg tablets - each film-coated tablet contains 120 mg of etoricoxib.

Inactive ingredients (Excipients):

- Magnesium stearate
- Calcium hydrogen phosphate anhydrous
- Purified water
- Titanium dioxide
- Microcrystalline cellulose
- Lactose monohydrate
- Triacetin
- Hypromellose 15cp
- Croscarmellose sodium
- Povidone

MAL Number

Coxitor 90mg Film-coated Tablets

MAL18116071ACZ

Coxitor 120mg Film-coated Tablets

MAL18116072ACZ

MANUFACTURER AND PRODUCT REGISTRATION HOLDER

Manufacturer

Cadila Pharmaceuticals Limited
1389 Trasad Road,
Dholka, Ahmedabad 382 225, INDIA

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Product Registration Holder

Sandoz Products Malaysia Sdn. Bhd.
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47400 Petaling Jaya Selangor, Malaysia

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