

COXETA FC TABLETS

Etoricoxib (60mg, 90mg, 120mg)

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What Coxeta is used for

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

Coxeta is also used for the short term treatment of moderate pain including that related to dental surgery and menstrual pain.

How Coxeta work

Coxeta is a member of a group of medicines called selective COX-2 inhibitors that are used to reduce pain and inflammation.

Before you use Coxeta

-When you must not take it

Do not take Coxeta if you:

- are allergic to etoricoxib and any of its ingredients
- have had heart failure, a heart attack, bypass surgery, peripheral arterial disease (poor circulation in legs or feet due to narrow or blocked arteries)
- have increased risk of heart disease such as a stroke. 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.
- have high blood pressure that has not been controlled by treatment.
- are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors

- have a current stomach ulcer or bleeding in your stomach or intestines
- have serious kidney disease
- are or could be pregnant or are breast-feeding
- have inflammatory bowel disease

If you think any of these are relevant to you, do not take the tablets until you have consulted your doctor.

Pregnancy and breast-feeding

Pregnancy

Coxeta 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 Coxeta. If you become pregnant, stop taking Coxeta 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 Coxeta. If you are using Coxeta, you must not breast-feed.

-Before you start to take it

Ask a doctor or pharmacist if you:

- have a history of stomach bleeding or ulcers.
- are dehydrated, for example by a prolonged bout of vomiting or diarrhoea.
- have swelling due to fluid retention.
- have a history of heart failure, or any other form of heart disease.
- 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.
- have any history of liver or kidney disease.
- are being treated for an infection. Etoricoxib can mask or hide a fever, which is a sign of infection.

- are a woman trying to become pregnant.
- are elderly (i.e., over 65 years of age).
- have diabetes, high cholesterol, or is a smoker. These can increase your risk of heart disease.
- 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.

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

-Taking 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 Coxeta:

- 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)
- birth control pills
- hormone replacement therapy
- aspirin, the risk of stomach ulcers is greater if you take Coxeta with aspirin.
- Coxeta 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

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- do not take high dose aspirin or other anti-inflammatory medicines while taking Coxeta.

How to take Coxeta

-How much to take

Your doctor will decide what dose of Coxeta you should take and how long you should take it. For treatment of osteoarthritis:

- The recommended dose is 30 mg or 60 mg once a day.

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.

For treatment of acute gouty arthritis:

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

For the relief of pain related to minor dental procedures and menstrual pain:

- The recommended dose is 90mg once daily for minor dental procedures and 120mg once daily for menstrual pain. Coxeta should be used only for the acute period limited to a maximum of 8 days.

Doses greater than those recommended for each condition have either not demonstrated additional efficacy or have not been studied. Therefore, the daily doses stated above for each condition should not be exceeded.

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

-When to take it

Coxeta should be taken once a day. You may take Coxeta with or without food.

-How long to take it

Always take Coxeta exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist. Continue taking Coxeta tablet for as long as your doctor recommends.

-If you forget to take it

If you forget to take Coxeta, take it as soon as you can. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

-If you take too much (overdose)

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately.

While you are taking Coxeta

-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 Coxeta.

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 Coxeta to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Be careful driving or operating machinery until you know how Coxeta affects you.

Side Effects

Like all medicines, Coxeta may cause side effects, although not everybody gets them.

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

Very Common

- abdominal pain

Common

- painful dental condition such as dry socket
- swelling of the legs and/or feet due to water retention
- dizziness, headache
- fast or irregular heartbeat, irregular heart rhythm, increased blood pressure
- tightening of muscles in the airways causing difficulty in breathing
- constipation, flatulence, inflammation of the stomach and oesophagus, stomach pain, heartburn, nausea, vomiting, diarrhea, oral ulcer
- changes in blood tests related to your liver
- bruising of the skin
- feeling tired and flu-like symptoms

Uncommon

- infections related to inflammation of the intestines, upper respiratory tract and urinary tract
- low blood count such as red blood, white blood cells and platelets
- increased or decreased appetite, weight gain
- anxiety, depression, decreases in mental sharpness; seeing, feeling or hearing things that are not there
- eye problems such as blurred vision and eye infection
- ringing in the ears or imbalance
- heart problems such as irregular or rapid heartbeat, heart failure, chest pain, heart attack
- yellowing of the skin and eyes (jaundice) and
- problems related to impaired blood flow to the brain or increased blood pressure resulting in stroke, inflammation of the blood vessels
- cough, shortness of breath, bleeding from the nose

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- accumulation of air or fluid in the abdomen, change in bowel movement pattern, dry mouth, ulcers in the intestines and stomach causing bleeding, disorder of the large intestine, inflammation of the pancreas
 - facial swelling, itchiness, redness and rashes
 - muscle cramps, pain or stiffness
 - high protein levels in the urine, kidney related problems such as high creatinine levels, kidney failure
 - chest pain
 - increase in blood urea nitrogen, creatinine phosphokinase, potassium levels and uric acid

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 Coxeta

-Storage

Keep all medicines out of the reach of children.
 Store below 30°C.
 Store in the original package.
 Protect from moisture and light.

-Disposal

Do not take this medicine after the expiry date stamped on the pack.
 Return any unused tablets to your pharmacist to be disposed of. Only keep the tablets if your doctor tells you to. Do not throw them away in your normal household drainage or waste. This will help to protect the environment.

Product Description

-What it looks like

Coxeta 60mg: Dark green, round, biconvex film-coated tablet, debossed "60" on one side and plain on the other.

Dimension: Approx. 8 mm diameter.

Coxeta 90mg: White, round, biconvex film-coated tablet, debossed "90" on one side and plain on the other.

Dimension: Approx. 9 mm diameter.

Coxeta 120mg: Pale-green, round, biconvex film-coated tablet, debossed "120" on one side and plain on the other.

Dimension: Approx. 10 mm diameter.

-Ingredients

Active Ingredient

Coxeta are tablets containing 60mg, 90mg, or 120mg etoricoxib as its active ingredient.

Inactive ingredients

Calcium hydrogen phosphate anhydrous, microcrystalline cellulose, crospovidone, povidone, magnesium stearate.

Coating material

AquaPolish P green 074.23 MS for 60mg which consists of hypromellose, talc, hydroxypropylcellulose, medium chain triglyceride, titanium dioxide, brilliant blue (Blue 1) Al-lake, Indigo carmine (Blue 2) Al-lake, iron oxide yellow and iron oxide black.

AquaPolish P white 014.44 MS for 90mg which consists of hypromellose, talc, hydroxypropylcellulose, medium chain triglyceride, titanium dioxide.

AquaPolish P green 074.25 MS for 120mg which consists of hypromellose, talc, hydroxypropylcellulose, medium chain triglyceride, titanium dioxide, brilliant blue (Blue 1) Al-lake, Indigo carmine (Blue 2) Al-lake, iron oxide yellow and iron oxide black.

-MAL Number

Coxeta 60mg:
 MAL21096006AZ

Coxeta 90mg:
 MAL21096007AZ

Coxeta 120mg:
 MAL21096008AZ

Manufacturer

TEVA Gyogyszergyar Zrt.
 Pallagi ut 13., Debrecen H-4042,
 Hungary

Product Registration Holder

DCH Auriga (Malaysia) Sdn.
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Date of Revision

25/05/2023

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