

PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

ECOXAR 30 mg Film coated tablets

ECOXAR 60 mg Film coated tablets

ECOXAR 90 mg Film coated tablets

ECOXAR 120 mg Film coated tablets

Etoricoxib

ECOXAR 30 mg: contains sugar: lactose monohydrate 1,05 mg per tablet.

ECOXAR 60 mg: contains sugar: lactose monohydrate 2,10 mg per tablet.

ECOXAR 90 mg: contains sugar: lactose monohydrate 3,15 mg per tablet.

ECOXAR 120 mg: contains sugar: lactose monohydrate 4,20 mg per tablet.

Read all of this leaflet carefully before you start taking ECOXAR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider
- ECOXAR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ECOXAR is and what it is used for
2. What you need to know before you take ECOXAR
3. How to take ECOXAR



4. Possible side effects
5. How to store ECOXAR
6. Contents of the pack and other information

1. WHAT ECOXAR is and what it is used for

ECOXAR belongs to a group of medicines called Anti-Rheumatics (Anti-inflammatory Agents) that help 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.

ECOXAR is also used for the short term treatment of moderate pain, pain after dental surgery in people 16 years of age and older for a maximum of 8 days.

ECOXAR is used for the treatment of painful period.

2. What you need to know before you take ECOXAR

Do not take ECOXAR:

- if you are hypersensitive (allergic) to etoricoxib or any of the other ingredients of ECOXAR (see section 6)
- if you are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors
- if you develop signs of asthma, a runny or blocked nose, growths in the nasal passage or itching and swelling of the skin (e.g., face, eyelids, mouth or tongue) after taking aspirin or other non-steroidal anti-inflammatory medicines(NSAIDs) including ECOXAR
- 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 and Breastfeeding'**)

- 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).
ECOXAR 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 are having bypass surgery.
- if you are over 65 years of age. Your doctor will want to appropriately keep a check on you if you are elderly and have kidney, liver or heart problems.

Warnings and precautions

ECOXAR should be taken for the shortest duration possible and the lowest effective daily dose should be used.

Take special care with ECOXAR:

if you are taking low-dose aspirin with ECOXAR as the rate of stomach ulcers or other stomach and intestine complications can increase

- ECOXAR is not a substitute for aspirin for cardiovascular prophylaxis because of its lack of effect on platelets
- if a serious skin reaction is noticed in patients with a history of any allergy
- If you have a history of stomach bleeding or ulcers
- if you are dehydrated, for example by a prolonged bout of vomiting or diarrhoea
- if you have swelling due to fluid retention
- if you have a history of heart failure, or any other form of heart disease
- if you have a history of high blood pressure. ECOXAR 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
- if you have any history of liver or kidney disease
- if you are being treated for an infection. ECOXAR can mask or hide a fever, which is a sign of infection
- if you have diabetes, high cholesterol, or are a smoker. These can increase your risk of heart disease
- if you are a woman trying to become pregnant
- if you are 20 weeks pregnant as ECOXAR can harm your unborn baby.
- if you develop an extensive skin rash that is accompanied by fever, swollen lymph nodes and swelling on the face. Inform your doctor immediately, as this can be life threatening.

3. How to take ECOXAR

Do not share medicines prescribed for you with any other person.

Always take ECOXAR exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

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

If you have the impression that the effect of ECOXAR is too strong or too weak, tell your doctor or pharmacist.

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

If you are elderly and have kidney, liver or heart problems, your doctor will want to appropriately keep a check on you. If you show deterioration during treatment with ECOXAR, your doctor will take appropriate measures, including stopping ECOXAR treatment.

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.

Osteoarthritis

The recommended dose is 30 mg once a day.

Rheumatoid arthritis

The recommended dose is 90 mg once a day.

Ankylosing spondylitis

The recommended dose is 90 mg once a day.

Acute pain conditions

The recommended dose is 90 or 120 mg once a day which should only be used for the acute painful period, limited to a maximum of 8 days treatment.

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.

Primary dysmenorrhea

The recommended dose is 120 mg once a day.

Postoperative dental surgery pain

The recommended dose is 90 mg once day.

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.

Elderly

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

If you take more ECOXAR than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ECOXAR:

It is important to take ECOXAR 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.

4. Possible side effects

ECOXAR can have side effects.

Not all side effects reported for ECOXAR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ECOXAR, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking ECOXAR and tell doctor immediately or go to the casualty department at your nearest hospital:

- 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, liver failure
- severe or continual stomach pain or your stools become black,
- a severe allergic reaction or hypersensitivity 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/anaphylactic/anaphylactoid reactions including shock (a serious allergic reaction that requires immediate medical attention).
- extensive skin rash that is accompanied by fever, swollen lymph nodes and swelling in the face (Drug reaction with eosinophilia and systemic symptoms (DRESS))

These are very serious side effects. If you/ have them you may have had a serious reaction to ECOXAR. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- palpitations (fast or irregular heartbeat), irregular heart rhythm (dysrhythmia),
- abnormal heart rhythm (atrial fibrillation), fast heart rate, heart failure, feeling of tightness, pressure or heaviness in the chest (angina pectoris), heart attack
- chest pain
- flushing, stroke, mini-stroke (transient ischaemic attack), severe increase in blood pressure, inflammation of the blood vessels,
- wheezing or shortness of breath (bronchospasms).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

- stomach pain
- dry socket (inflammation and pain after a tooth extraction)
- swelling of the legs and/or feet due to fluid retention (oedema)
- dizziness, headache
- increased blood pressure
- 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
- weakness and fatigue, flu-like illness
- changes in blood tests related to your liver

Less frequent or frequency unknown

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

- changes in laboratory values (decreased number of red blood cells, decreased number of white blood cells, platelets decreased)
- 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)
- 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
- confusion, restlessness
- liver problems (hepatitis)
- low blood levels of sodium

In clinical studies, a higher incidence of adverse experiences was seen in older patients compared to younger patients.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Reporting side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of ECOXAR.

6. How to store ECOXAR

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from moisture. Keep blister in carton until required for use.

Do not use after the expiry date stated on the label or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ECOXAR contains

The active substance is etoricoxib.

ECOXAR 30 mg

Each film coated tablet contains etoricoxib 30 mg.

Contains sugar: lactose monohydrate 1,05 mg/coated tablet.

ECOXAR 60 mg

Each film coated tablet contains etoricoxib 60 mg.

Contains sugar: lactose monohydrate 2,10 mg/coated tablet.

ECOXAR 90 mg

Each film coated tablet contains etoricoxib 90 mg.

Contains sugar: lactose monohydrate 3,15 mg/coated tablet.

ECOXAR 120 mg

Each film coated tablet contains etoricoxib 120 mg.

Contains sugar: lactose monohydrate 4,20 mg/coated tablet.

The other ingredients are: Cellulose microcrystalline, calcium hydrogen phosphate anhydrous, croscarmellose sodium, magnesium stearate

As coating agent for:

30 mg: Opadry II green 32K510020 (lactose monohydrate, hypromellose, titanium dioxide, triacetin, indigo carmine aluminium lake, iron oxide yellow)

60 mg: Opadry II green 35K510000 (lactose monohydrate, hypromellose, titanium dioxide, triacetin, indigo carmine aluminium lake, iron oxide yellow)

90 mg: Opadry II white 35K580003 (lactose monohydrate, hypromellose, titanium dioxide, triacetin)

120 mg: Opadry II green 32K510018 (lactose monohydrate, hypromellose, titanium dioxide, triacetin, indigo carmine aluminium lake, iron oxide yellow)

What ECOXAR looks like and contents of the pack

ECOXAR 30 mg

Blue green, film coated, round biconvex tablets, E30 debossed on one side and plain on other side.

ECOXAR 60 mg

Green to dark green, film coated, round biconvex tablets, E60 debossed on one side and plain on other side.

ECOXAR 90 mg

White to off white, film coated, round biconvex tablets, E90 debossed on one side and plain on other side.

ECOXAR 120 mg

Light green to pale green, film coated round biconvex tablets, E120 debossed on one side and plain on other side.

The tablets are packed in cold form blisters. Each blister strip contains 7 tablets. Carton contains 7 or 28 tablets.

Cold form blister pack

Cold form blister pack comprises of cold form blister laminate composed of oriented polyamide, aluminium foil and PVC film with backing of hard tempered aluminium foil coated with heat seal lacquer on the inner side.

Holder of Certificate of Registration

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