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). 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 are having bypass surgery.

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.
- 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.

Children and adolescents

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

Other medicines and ECOXAR

Always tell your health care professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the medicines listed below:

- 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)
- ciclosporin or tacrolimus (medicines used for suppressing the immune system)
- lithium (a medicine used to treat some types of depression) as taking lithium together with ECOXAR may lead to toxic blood concentration of lithium
- 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
- diuretics (water tablets)
- 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 (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 ECOXAR with aspirin.
  - aspirin for prevention of heart attacks or stroke:

ECOXAR 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

- aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs):

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

ECOXAR with food and drink:

ECOXAR can be taken with or without food.

Pregnancy, breastfeeding and Fertility:

Do not take ECOXAR if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby while taking ECOXAR, please consult your doctor, pharmacist or other health care professional for advice before taking ECOXAR.

Pregnant women should not use NSAIDs (pain medicine) such as ECOXAR at 20 weeks or later unless specifically advised to do so by health care professional because these medicines may cause problems in an unborn baby.

Driving and using machines:

Dizziness and sleepiness have been reported in some patients taking ECOXAR

Do not drive if you experience dizziness or sleepiness.

Do not use any tools or machines if you experience dizziness or sleepiness.

ECOXAR contains lactose:

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

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 "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. 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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PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS S3

ECOXAR 30 mg Filmbedekte tablette

ECOXAR 60 mg Filmbedekte tablette

ECOXAR 90 mg Filmbedekte tablette

ECOXAR 120 mg Filmbedekte tablette

Etorikoksib

ECOXAR 30 mg: bevat suiker: 1,05 mg laktosemonohidraat per tablet.

ECOXAR 60 mg: bevat suiker: 2,10 mg laktosemonohidraat per tablet.

ECOXAR 90 mg: bevat suiker: 3,15 mg laktosemonohidraat per tablet.

ECOXAR 120 mg: bevat suiker: 4,20 mg laktosemonohidraat per tablet.

Lees hierdie hele inligtingsblad aandagtig deur voordat jy begin om ECOXAR te neem

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Vra gerus jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer indien jy nog vrae het.
- ECOXAR is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met ander mense deel nie. Dit kan skadelik wees vir hulle, al het hulle dieselfde simptome as jy.

Wat is in hierdie inligtingsblad

1. Wat is ECOXAR en waarvoor word dit gebruik

2. Wat jy moet weet voordat jy ECOXAR neem

3. Hoe om ECOXAR te neem

4. Moontlike newe-effekte

5. Hoe om ECOXAR te bêre

6. Inhoud van die pak en ander inligting.

1. Wat is ECOXAR en waarvoor word dit gebruik

ECOXAR behoort aan ’n groep medisyne genaamd antirumatika (antiinflammatoriese middels) wat help om die pyn en swelling (inflammasie) in die gewrigte en spiere van persone van 16 jaar en ouer met osteoartritis, rumatoïede artritis, ankiloserende spondilitis en jig te verlig.

ECOXAR word ook vir die korttermynbehandeling van matige pyn en pyn na tandheelkundige chirurgie in persone van 16-jarige ouderdom en ouer gebruik, vir ’n maksimum van 8 dae.

ECOXAR word vir die behandeling van pynlike menstruasie gebruik.

2. Wat jy moet weet voordat jy ECOXAR neem

Moenie ECOXAR neem nie:

- indien jy hipersensitief (allergies) is vir etorikoksib of enige van die ander bestanddele van ECOXAR (sien afdeling 6)
- indien jy allergies is vir niesteroïdale antiinflammatoriese geneesmiddels (NSAIM's), insluitende aspirien en COX-2-inhibeerders
- indien jy tekens van asma, ’n loopneus of toe neus, vergroeisels in die neusgange of gejeuk en swelling van die vel (bv. gesig, ooglede, mond of tong) ontwikkel nadat jy aspirien of ander niesteroïdale antiinflammatoriese geneesmiddels (NSAIM's), insluitende ECOXAR, geneem het
- indien jy tans ’n maagseer of bloeding in jou maag of ingewande het
- indien jy ernstige lewersiekte het
- indien jy ernstige niersiekte het
- indien jy swanger is of moontlik swanger kan wees, of jou baba borsvoed (**sien "Swangerskap en Borsvoeding"**)
- indien jy jonger as 16 jaar is
- indien jy inflammatoriese dermsiekte het, soos Crohn se siekte, ulseratiewe kolitis, of kolitis
- indien jy hoë bloeddruk het wat nie met behandeling beheer word nie (bevestig met jou dokter of verpleegster indien jy onseker is of jou bloeddruk voldoende beheer word)
- indien jou dokter jou met hartprobleme gediagnoseer het, insluitende hartversaking (matige of ernstige tipes), angina (borspyn)
- indien jy ’n hartaanval, omleidingchirurgie, perifere slagaarsiekte (swak sirkulasie in die bene of voete as gevolg van nou of verstopte are) gehad het
- indien jy enige tipe beroerte gehad het (insluitende mini-beroerte, vlietende iskemiese aanval of TIA). Etorikoksib kan jou risiko vir hartaanval en beroerte effens verhoog en dit is waarom dit nie gebruik moet word by diegene wat alreeds hartprobleme of beroerte gehad het nie
- indien jy omleidingchirurgie ondergaan.

Waarskuwings en voorsorgmaatreëls

ECOXAR behoort vir die kortste moontlike tydperk geneem te word en die laagste effektiewe dosis moet geneem word.

Neem spesiale sorg met ECOXAR

- indien jy lae-dosis aspirien saam met ECOXAR neem, aangesien die voorkoms van maagsere en ander maag- en ingewandskomplikasies kan verhoog
- ECOXAR is nie ’n plaasvervanger vir aspirien vir kardiovaskulêre profilakse nie weens die gebrek aan effek op plaatjies
- indien ’n ernstige velreaksie by pasiënte met ’n geskiedenis van enige allergie opgemerk word
- indien jy ’n geskiedenis van maagbloeding of maagsere het
- indien jy ontwater is, byvoorbeeld weens langdurige braking of diarree
- indien jy swelling het as gevolg van vogterughouding
- **indien jy ’n geskiedenis van hartversaking of enige ander vorm van hartsiekte het**
- indien jy ’n geskiedenis van hoë bloeddruk het. ECOXAR kan bloeddruk by sommige persone verhoog, veral wanneer hoë dosisse geneem word, en jou dokter sal jou bloeddruk van tyd tot tyd wil nagaan
- indien jy enige geskiedenis van lewer- of niersiekte het
- indien jy vir ’n infeksie behandel word. ECOXAR kan koors, wat ’n teken van infeksie is, maskeer of verberg
- indien jy diabetes of hoë cholesterol het, of ’n roker is. Hierdie faktore kan jou risiko vir hartsiekte verhoog
- indien jy ’n vrou is wat probeer om swanger te raak
- indien jy 20 weke of meer swanger is, aangesien ECOXAR skadelik kan wees vir jou ongebore baba
- as jy 'n uitgebreide veluitslag ontwikkel wat met koors, geswelde limfknope en gesigswelling gepaard gaan. Stel jou dokter dadelik in kennis, aangesien dit lewensgevaarlik kan wees.

- indien jy ouer as 65 jaar is. Jou dokter sal behoorlike toesig oor jou wil hou as jy bejaard is en nier-, lewer- of hartprobleme het.

Kinders en adolessente

ECOXAR moenie deur kinders of adolessente jonger as 16 jaar geneem word nie.

Ander medisyne en ECOXAR

Sê altyd vir jou gesondheidsorgdeskundige indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

Lig jou dokter in indien jy enige van die medisyne wat hier onder genoem word neem:

- medisyne wat jou bloed verdun (antikoagulante), soos warfarien
- rifampisien (’n antibiotikum)
- metotreksaat (’n medisyne wat gebruik word om die immuunstelsel te onderdruk, en dikwels gebruik word vir rumatoïede artritis)
- siklosporien of takrolimus (medisyne wat gebruik word om die immuunstelsel te onderdruk)
- litium (’n medisyne wat gebruik word om sekere soorte depressie te behandel) aangesien die neem van litium saam met ECOXAR tot toksiese bloedvlakke van litium kan lei
- medisyne wat gebruik word om hoë bloeddruk en hartversaking te help beheer, genoem AOE-inhibeerders en angiotensienreseptorblokkeerders, voorbeelde sluit enalapriel en ramipriel, en losartaan en valsartaan in
- diuretika (waterpille)
- digoksien (’n medisyne vir hartversaking en onreëlmatige hartritme)
- minoksidiel (’n middel wat gebruik word om hoë bloeddruk te behandel)
- salbutamol tablette of mondelikse oplossing (’n medisyne gebruik vir asma)
- geboortebeperkingspille (die kombinasie kan jou risiko vir newe-effekte verhoog)
- hormoonvervangingsterapie (die kombinasie kan jou risiko vir newe-effekte verhoog)
- aspirien, die risiko van maagsere is groter as jy ECOXAR saam met aspirien neem.

- aspirien vir die voorkoming van hartaanvalle of beroerte:

  ECOXAR kan saam met lae-dosis aspirien geneem word. Indien jy tans lae–dosis aspirien neem om hartaanvalle of beroerte te voorkom, moet jy nie ophou om aspirien te neem voordat jy met jou dokter daaroor gepraat het nie
- aspirien en ander niesteroïdale antiinflammatoriese geneesmiddels (NSAIM's):

  moenie hoë dosisse aspirien of ander antiinflammatoriese middels gebruik terwyl jy ECOXAR neem nie.

ECOXAR met kos en drinkgoed:

ECOXAR kan met of sonder kos geneem word.

Swangerskap, borsvoeding en vrugbaarheid:

Moenie ECOXAR neem indien jy swanger is of jou baba borsvoed nie.

Indien jy swanger is of jou baba borsvoed terwyl jy ECOXAR neem, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgdeskundige vir advies voordat jy ECOXAR neem.

Swanger vrouens behoort nie NSAIM's (pynmedisyne) soos ECOXAR te neem wanneer hulle 20 weke of meer swanger is nie, behalwe indien hulle uitdruklik deur ’n gesondheidsorgdeskundige geadviseer is om dit te neem, aangesien hierdie medisyne nadelig vir die ongebore baba kan wees.

Bestuur en die gebruik van masjiene:

Duiseligheid en slaperigheid is gerapporteer by sommige pasiënte wat ECOXAR neem.

Moenie bestuur indien jy duiselig of slaperig voel nie.

Moenie enige gereedskap of masjiene gebruik indien jy duiseligheid of slaperigheid ervaar nie.

ECOXAR bevat laktose:

Indien jou dokter jou ingelig het dat jy ’n onverdraagsaamheid vir sekere suikers het, kontak jou dokter voordat jy ECOXAR neem.

3. Hoe om ECOXAR te neem

Moenie medisyne wat vir jou voorgeskryf is, met iemand anders deel nie.

Neem ECOXAR altyd presies soos wat jou dokter of apteker vir jou aangedui het. Vra gerus jou dokter of apteker indien jy onseker is.
ECOXAR is vir mondelikse gebruik. Neem die tablette een keer per dag. ECOXAR kan met of sonder kos geneem word.
Indien jy die indruk kry dat die effek van ECOXAR te sterk of te swak is, bespreek dit met jou dokter of apteker.

Moenie meer neem as die dosis wat vir jou toestand aanbeveel word nie. Jou dokter sal jou behandeling van tyd tot tyd met jou wil bespreek. Dit is belangrik dat jy die laagste dosis wat nodig is om jou pyn te beheer gebruik en jy moet nie ECOXAR vir langer as wat nodig is neem nie. Dit is omdat die risiko vir hartaanvalle en beroerte kan toeneem na langdurige behandeling, veral met hoë dosisse.

Indien jy ’n bejaarde persoon is en nier-, lewer- of hartprobleme het, sal jou dokter jou behoorlik wil dophou. As jy agteruitgang toon tydens behandeling met ECOXAR**,** sal jou dokter toepaslike maatreëls instel, insluitende staking van ECOXAR-behandeling.

Daar is verskillende sterktes van hierdie medisinale produk beskikbaar en jou dokter sal die tablet met die sterkte wat vir jou geskik is afhangende van jou siekte, voorskryf.

Osteoartritis

Die aanbevole dosis is 30 mg een keer per dag.

Rumatoïede artritis

Die aanbevole dosis is 90 mg een keer per dag.

Ankiloserende spondilitis

Die aanbevole dosis is 90 mg een keer per dag.

Toestande van akute pyn

Die aanbevole dosis is 90 mg of 120 mg een keer per dag, wat slegs vir die tydperk van akute pyn gebruik moet word, beperk tot ’n maksimum van 8 dae se behandeling.

Jig

Die aanbevole dosis is 120 mg een keer per dag, wat slegs vir die tydperk van akute pyn gebruik moet word, beperk tot ’n maksimum van 8 dae se behandeling.

Primêre dismenorree

Die aanbevole dosis is 120 mg een keer per dag.

Postoperatiewe tandheelkundige pyn

Die aanbevole dosis is 90 mg een keer per dag.

Persone met lewerprobleme

Indien jy aan ’n geringe lewersiekte ly, behoort jy nie meer as 60 mg per dag te neem nie.

Indien jy matige lewersiekte het, behoort jy nie meer as 30 mg per dag te neem nie.

Bejaarde persone

Dit is nie nodig om die dosis vir bejaarde pasiënte aan te pas nie. Soos met ander medisyne, is versigtigheid nodig by bejaarde pasiënte.

Wat om te doen indien jy meer ECOXAR geneem het as wat jy moet:

In geval van oordosering, konsulteer jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien jy vergeet om ECOXAR te neem:

Dit is belangrik om ECOXAR te neem soos jou dokter dit voorgeskryf het. Indien jy ’n dosis oorgeslaan het, gaan net die volgende dag voort met die gewone skedule. Moenie ’n dubbele dosis neem om te vergoed vir die dosis wat oorgeslaan is nie.

4. Moontlike newe-effekte

ECOXAR kan newe-effekte hê.

Nie alle newe-effekte wat vir ECOXAR gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy ECOXAR neem, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgdeskundige.

Indien enige van die volgende gebeur, hou op om ECOXAR te neem en sê dadelik vir jou dokter of gaan na die ongevalleafdeling by jou naaste hospitaal:

- kortasemheid, borspyn, of as swelling van die enkels voorkom of as dit vererger
- vergeling van die vel en oë (geelsug) – hierdie is tekens van lewerprobleme, lewerversaking
- erge of aanhoudende maagpyn of as jou stoelgang swart word
- ’n erge allergiese reaksie of hipersensitiwiteitsreaksie – wat velprobleme soos ulkusse of blaasvorming, of swelling van die gesig, lippe, tong of keel, wat probleme met asemhaling kan veroorsaak, anafilaktiese/anafilaktoïede reaksies, insluitende skok (’n ernstige allergiese reaksie wat onmiddellike mediese bystand vereis) kan insluit.
- uitgebreide veluitslag wat gepaard gaan met koors, geswelde limfknope en swelling in die gesig (Geneesmiddelreaksie met eosinofilie en sistemiese simptome (DRESS))

Hierdie is baie ernstige newe-effekte. Jy mag ’n ernstige reaksie op ECOXAR gehad het as jy dit het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Sê dadelik vir jou dokter of gaan na die ongevalleafdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:

- hartkloppings (vinnige of onreëlmatige hartklop), onreëlmatige hartritme (disritmie),
- abnormale hartritme (atriale fibrillasie), vinnige hartspoed, hartversaking, benoude gevoel, drukking of swaar gevoel in die borskas (angina pectoris), hartaanval
- borskaspyn
- blosing, beroerte, mini-beroerte (vlietende iskemiese aanval), erge verhoging in bloeddruk, inflammasie van die bloedvate
- hyg of kortasemheid (brongospasma).

Hierdie is ernstige newe-effekte. Jy mag dringend mediese bystand nodig hê.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Newe-effekte wat dikwels voorkom

- maagpyn
- droë tandkas (inflammasie en pyn nadat ’n tand getrek is)
- swelling van die bene en/of voete as gevolg van vloeistofterughouding (edeem)
- duiseligheid, hoofpyn
- verhoogde bloeddruk
- hardlywigheid, winderigheid (oormatige gas), gastritis (inflammasie van die voering van die maag), sooibrand, diarree, slegte spysvertering (dispepsie)/maagongemak, naarheid, braking, inflammasie van die slukderm, sere in die mond
- swakheid en uitputting, griepagtige siektetoestand
- veranderinge in bloedtoetse wat verband hou met jou lewer

Minder dikwels of voorkoms onbekend

- kneusing
- gastroënteritis (inflammasie van die gastroïntestinale kanaal wat beide die maag en dunderm/maag insluit), boonstelugweginfeksie, urienweginfeksie

- veranderings in laboratoriumwaardes (verlaagde getal rooibloedselle, verlaagde getal witbloedselle, afname in plaatjies)
- verminderde of verhoogde eetlus, gewigstoename
- angstigheid, depressie, afname in verstandelike waaksaamheid; sien, voel of hoor dinge wat nie bestaan nie (hallusinasies)
- smaakveranderinge, onvermoë om te slaap, gevoelloosheid of tinteling, slaperigheid
- belemmerde visie, oogirritasie en rooiheid
- suising in die ore, vertigo (sensasie van draaiing terwyl jy stilstaan)
- hoes, uitasem, neusbloeding
- maag- of dermongemak, veranderings in jou dermgewoontes, droë mond, maagseer, inflammasie van die voering van die maag wat ernstig kan raak en kan lei tot bloeding, prikkelbaredermsindroom, inflammasie van die pankreas
- swelling van die gesig, veluitslag of jeukerige vel, rooiheid van die vel
- spierkrampe/spasmas, spierpyn/styfheid
- hoë vlakke van kalium in jou bloed, veranderinge in bloed- of urientoetse wat verband hou met die niere, ernstige nierprobleme
- verwardheid, rusteloosheid
- lewerprobleme (hepatitis)
- lae natriumvlakke in die bloed

In kliniese studies is ’n hoër voorkoms van ongewenste ervarings waargeneem by ouer pasiënte vergeleke met jonger pasiënte.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad gelys word nie, lig asseblief jou dokter of apteker daarvan in.

Rapportering van newe-effekte

Indien jy newe-effekte ondervind, bespreek dit met jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA rapporteer via die vorm om ongunstige geneesmiddelreaksies te rapporteer, wat aanlyn by SAHPRA se publikasies beskikbaar is: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van ECOXAR te verskaf.

6. Hoe om ECOXAR te bêre

Bewaar alle medisyne buite bereik van kinders.

Bewaar by of onder 25 °C. Beskerm teen vog. Hou die stulpstrook in die karton tot nodig vir gebruik.

Moenie gebruik ná die vervaldatum wat op die etiket of karton voorkom nie.

Neem alle ongebruikte medisyne terug na jou apteker.

Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat ECOXAR bevat

Die aktiewe bestanddeel is etorikoksib.

ECOXAR 30 mg

Elke filmbedekte tablet bevat 30 mg etorikoksib.

Bevat suiker: 1,05 mg laktosemonohidraat/filmbedekte tablet.

ECOXAR 60 mg

Elke filmbedekte tablet bevat 60 mg etorikoksib.

Bevat suiker: 2,10 mg laktosemonohidraat/filmbedekte tablet.

ECOXAR 90 mg

Elke filmbedekte tablet bevat 90 mg etorikoksib.

Bevat suiker: 3,15 mg laktosemonohidraat/filmbedekte tablet.

ECOXAR 120 mg

Elke filmbedekte tablet bevat 120 mg etorikoksib.

Bevat suiker: 4,20 mg laktosemonohidraat/filmbedekte tablet.

Die ander bestanddele is: mikrokristallyne sellulose, anhidriese kalsiumwaterstoffosfaat, natriumkroskarmellose, magnesiumstearaat.

As deklaag vir:

30 mg: Opadry II groen 32K510020 (laktosemonohidraat, hipromellose, titaandioksied, triasetien, indigo-karmyn aluminiumlak, geel ysteroksied)

60 mg: Opadry II groen 35K510000 (laktosemonohidraat, hipromellose, titaandioksied, triasetien, indigo-karmyn aluminiumlak, geel ysteroksied)

90 mg: Opadry II wit 35K580003 (laktosemonohidraat, hipromellose, titaandioksied, triasetien)

120 mg: Opadry II groen 32K510018 (laktosemonohidraat, hipromellose, titaandioksied, triasetien, indigo-karmyn aluminiumlak, geel ysteroksied).

Hoe ECOXAR lyk en inhoud van die verpakking

ECOXAR 30 mg

Blougroen, filmbedekte, ronde, bikonvekse tablette, met E30 aan die een kant ingepers en skoon aan die ander kant.

ECOXAR 60 mg

Groen tot donkergroen, filmbedekte, ronde, bikonvekse tablette, met E60 aan die een kant ingepers en skoon aan die ander kant.

ECOXAR 90 mg

Wit tot naaswit, filmbedekte, ronde, bikonvekse tablette, met E90 aan die een kant ingepers en skoon aan die ander kant.

ECOXAR 120 mg

Liggroen tot dowwe groen, filmbedekte, ronde, bikonvekse tablette, met E120 aan die een kant ingepers en skoon aan die ander kant.

Die tablette word in koudgevormde stulpstroke verpak. Elke stulpstrook bevat 7 tablette. Die karton bevat 7 of 28 tablette.

Koudgevormde stulpstroke

'n Koudgevormde stulpstrook bestaan uit koudgevormde stulpstrooklaminaat saamgestel uit georiënteerde poliamied, aluminiumfoelie en PVC-film met 'n agterkant van harde, getemperde aluminiumfoelie, bedek met hitteseëllak aan die binnekant.

Houer van Registrasiesertifikaat

Ranbaxy Pharmaceuticals (Edms.) Bpk.

Lautreweg 14

Stormill, Uitbr.1

Roodepoort 1724

Suid-Afrika

Hierdie inligtingsblad is laas hersien in

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Registrasienommers

ECOXAR 30 mg: 51/3.1/1144

ECOXAR 60 mg: 51/3.1/1145

ECOXAR 90 mg: 51/3.1/1146

ECOXAR 120 mg: 51/3.1/1147

Bemark deur Unicorn Pharmaceuticals (Edms.) Bpk.

* ECOXAR 30 mg word nie bemark nie. Vir hierdie dosis kan 30 mg etorikoksib van 'n ander handelsmerk gebruik word.