

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

ETORICOXIB 60 BIOTECH tablet
ETORICOXIB 90 BIOTECH tablet
ETORICOXIB 120 BIOTECH tablet

Read all of this leaflet carefully before you start taking ETORICOXIB BIOTECH

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ETORICOXIB BIOTECH 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.

1. WHAT ETORICOXIB BIOTECH CONTAINS

The active substance is etoricoxib.
ETORICOXIB 60 BIOTECH: Each tablet contains 60 mg of etoricoxib.
ETORICOXIB 90 BIOTECH: Each tablet contains 90 mg of etoricoxib.
ETORICOXIB 120 BIOTECH: Each tablet contains 120 mg of etoricoxib.

The other ingredients are:

Core:

Calcium phosphate dibasic (anhydrous), croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, and microcrystalline cellulose

Coating:

The 60 mg tablet contains Opadry II 32K510024 Green, consisting of FD&C Blue #2 / Indigo Carmine Aluminium Lake, HPMC 2910 / Hypromellose, iron oxide yellow, lactose monohydrate, titanium dioxide, triacetin.
The 90 mg tablet contains Opadry II 32K580000 White consisting of HPMC 2910 / Hypromellose, lactose monohydrate, titanium dioxide, triacetin.
The 120 mg tablet contains Opadry II 32K510022 Green consisting of FD&C Blue #2 / Indigo Carmine Aluminium Lake, HPMC 2910 / Hypromellose, iron oxide yellow, lactose monohydrate, titanium dioxide, triacetin.
ETORICOXIB BIOTECH tablets contain sugar (lactose monohydrate): 1,68 mg per 60 mg tablet; 2,52 mg per 90 mg tablet and 3,36 mg per 120 mg tablet.

2. WHAT ETORICOXIB BIOTECH IS USED FOR

ETORICOXIB BIOTECH is a non-steroidal anti-inflammatory medicine (NSAID) that relieves inflammation, pain and fever. ETORICOXIB BIOTECH belongs to a group of medicines known as selective COX-2 inhibitors. ETORICOXIB BIOTECH is used to reduce the symptoms of inflammation (pain and swelling) in joints and muscles of patients with rheumatoid arthritis as well as gouty arthritis (build-up of uric acid crystals in joints leading to pain and inflammation).

ETORICOXIB BIOTECH is also used for the treatment of:

- ankylosing spondylitis (a form of arthritis that primarily affects the spine; inflammation of the spinal joints)
- short term relief of acute pain (treatment limited to a maximum period of 8 days)
- acute pain after dental surgery
- menstrual pain

3. BEFORE YOU TAKE ETORICOXIB BIOTECH

Do not take ETORICOXIB BIOTECH:

- if you are hypersensitive (allergic) to etoricoxib or any of the other ingredients of ETORICOXIB BIOTECH
- if you have a stomach ulcer or are bleeding from the stomach or intestines
- if you have serious liver disease
- if you have serious kidney disease
- if you are allergic to aspirin or other non-steroidal anti-inflammatory medicines (NSAIDs) including COX-2 inhibitors such as ETORICOXIB BIOTECH or experienced any signs of allergy while using these medicines such as difficulty breathing, runny nose or itching
- if you have high blood pressure which is not under control
- if you are pregnant or breastfeeding your baby
- if you are under the age of 16 years
- if you have inflammatory bowel disease
- if you have congestive heart failure
- if you have heart disease 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 had any kind of stroke (including mini-stroke or transient ischaemic attack)
- if you have to undergo bypass surgery
- if you are currently being treated with lithium (treatment of bipolar disorders)
- if you are currently being treated with digoxin (treatment of heart failure)

Take special care with ETORICOXIB BIOTECH:

The use of ETORICOXIB BIOTECH may result in serious heart and circulation events, gastrointestinal events or skin reactions which may be fatal.

Talk to your doctor or pharmacist before taking ETORICOXIB BIOTECH if:

- You have any history of liver or kidney disease.
- You are dehydrated, for example by a prolonged vomiting or diarrhoea.
- You have swelling due to fluid retention.
- You have a history of heart failure, or any other form of heart disease.
- You have diabetes, high cholesterol, or are a smoker. These can increase your risk of heart complications.
- You have a history of high blood pressure. ETORICOXIB BIOTECH 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 a history of any medicine allergy. You might be at higher risk for serious skin reactions.
- You have a history of stomach bleeding or ulcers.
- You are being treated for an infection. ETORICOXIB BIOTECH can mask or hide a fever, which is a sign of infection.
- You are a woman trying to become pregnant.
- You are over 65 years of age.
- You are on warfarin or any other anticoagulant treatment. Your doctor will monitor your bleeding time.

If you have experienced any hypersensitivity (allergic) reaction to aspirin, you should avoid taking ETORICOXIB BIOTECH.

Taking ETORICOXIB BIOTECH with food and drink:

ETORICOXIB BIOTECH may be taken with or after food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking ETORICOXIB BIOTECH. ETORICOXIB BIOTECH should not be taken during pregnancy or if you are breastfeeding your baby.

Driving and using machinery:

You may experience dizziness or drowsiness (somnolence) while taking ETORICOXIB BIOTECH. Do not drive or operate machinery if you experience dizziness or sleepiness.

Important information about some of the ingredients of ETORICOXIB BIOTECH:

ETORICOXIB BIOTECH contains lactose (milk sugar). If you know that you are unable to digest and metabolise lactose (lactose intolerance), tell your doctor before taking ETORICOXIB BIOTECH.

Taking other medicines with ETORICOXIB BIOTECH:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

If you are taking any of the following medicines, your doctor may want to adjust your medicines once you start taking ETORICOXIB BIOTECH:

- ciclosporin or tacrolimus (drugs used for suppressing the immune system)
- 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)
- diuretics (water tablets)
- medicines used to help control high blood pressure and heart failure called ACE inhibitors and angiotensin receptor blockers, such as enalapril and ramipril, and losartan and valsartan
- lithium (a medicine used to treat some types of depression)
- birth control pills (the combination may increase your risk of side effects)
- hormone replacement therapy (the combination may increase your risk of side effects)
- 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)
- aspirin, the risk of stomach ulcers is greater if you take ETORICOXIB BIOTECH with aspirin.

Aspirin for prevention of heart attacks or stroke:

ETORICOXIB BIOTECH 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 ETORICOXIB BIOTECH.

4. HOW TO TAKE ETORICOXIB BIOTECH

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

Always take ETORICOXIB BIOTECH exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. ETORICOXIB BIOTECH is taken orally. ETORICOXIB BIOTECH may be taken with or without food. Use the lowest effective dose for the shortest possible period of time.

Rheumatoid Arthritis:

The recommended dose is 90 mg once daily. In some patients, the 60 mg once daily dose may provide adequate therapeutic benefit. The dose for rheumatoid arthritis should not exceed 90 mg daily.

Ankylosing Spondylitis (inflammation of the spinal joints):
The recommended dose is 90 mg once daily. The dose for ankylosing spondylitis should not exceed 90 mg daily.

Short term relief of acute pain:

The recommended dose is 90 mg or 120 mg once daily, limited to a maximum of 8 days treatment. The dose for acute pain should not exceed 120 mg daily.

Acute Gouty Arthritis:

The recommended dose is 120 mg once daily. ETORICOXIB 120 BIOTECH should be used only for the acute symptomatic period, limited to a maximum of 8 days treatment. The dose for acute gout should not exceed 120 mg daily.

Menstrual pain:

The recommended dose is 120 mg once daily. The dose for primary dysmenorrhoea should not exceed 120 mg daily.

Acute pain after dental surgery:

The recommended dose is 90 mg once daily. The dose for post-operative dental surgery pain should not exceed 90 mg daily.

Use in children and adolescents:

ETORICOXIB BIOTECH tablets should not be taken by children or adolescents under 16 years of age.

Elderly:

No adjustment of dose in ETORICOXIB BIOTECH is necessary for elderly patients, although the elderly may be more susceptible to side effects. Your doctor will intensify your monitoring if you are elderly with kidney, liver or heart dysfunction.

Patients 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 60 mg every other day.

Your doctor will tell you how long your treatment with ETORICOXIB BIOTECH will last.

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

If you take more ETORICOXIB BIOTECH than you should:

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

If you forget to take / miss a dose of ETORICOXIB BIOTECH:

If you forget to take a dose, just resume your usual schedule the following day. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

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

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

- shortness of breath, chest pains, or ankle swelling appear or if they get worse
 - yellowing of the skin and eyes, also called jaundice – these are signs of liver problems
 - severe or continual stomach pain or your stools become black
 - an allergic reaction - swelling of the face, lips, tongue or throat, which may cause difficulty in swallowing or breathing
 - skin problems such as such as ulcers or blistering
- These are all very serious side effects. If you have them, you may have had a serious reaction to ETORICOXIB BIOTECH. 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:

- irregular heart rhythm (dysrhythmia), fast or irregular heart rate, severe increase in blood pressure
 - abnormal heart rhythm (atrial fibrillation), heart failure, feeling of tightness, pressure or heaviness in the chest (angina pectoris), heart attack, flushing, stroke
 - mini-stroke (transient ischaemic attack)
 - decreased number of red blood cells, decreased number of white blood cells decreased number of platelets
 - anaemia (as a result of gastrointestinal bleeding).
- These are all serious side effects. You may need urgent medical attention.

The following side effects can occur during treatment with ETORICOXIB BIOTECH:

Frequent side effects:

- 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
- stomach pain, wind (excessive gas), heartburn, diarrhoea, indigestion (dyspepsia), stomach discomfort, nausea
- bruising
- weakness and fatigue, flu-like illness
- changes in blood tests related to your liver

Less frequent side effects:

- gastroenteritis (inflammation of the gastrointestinal tract that involves both the stomach and small intestine/ stomach flu), upper respiratory infection, urinary tract infection
- appetite increases or decreases, weight gain
- anxiety, depression, decreases in mental sharpness
- inability to sleep, numbness or tingling
- eye irritation and redness
- ringing in the ears, vertigo (sensation of spinning while remaining still)
- inflammation of the blood vessels
- cough, breathlessness, nosebleed
- stomach or bowel bloating, acid reflux, changes in your bowel habits, constipation, gastritis (inflammation of the lining of the stomach), being sick (vomiting)
- dry mouth, stomach ulcer, irritable bowel syndrome, inflammation of the pancreas
- inflammation of the oesophagus, mouth ulcers
- 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
- low blood levels of sodium

The frequency of the following side effects is unknown:

- hypersensitivity (an allergic reaction including hives which may be serious enough to require immediate medical attention)
 - confusion, restlessness
 - feeling or hearing things that are not there (hallucinations)
 - taste alteration, sleepiness
 - blurred vision
 - inflammation of the stomach lining that can become serious and may lead to bleeding
 - severe skin reactions
- If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF ETORICOXIB BIOTECH

Store at or below 30 °C.

Store in the original package.

Protect from moisture.

Keep blisters in outer carton until required for use.

Keep all medicines out of reach of children.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF ETORICOXIB BIOTECH

ETORICOXIB BIOTECH are packed as follow:

- ETORICOXIB 60 BIOTECH: 28 Tablets blister of Aluminium foil and CFB or PVC/PVDC or PVC/PE/PVDC foil in cardboard box.
- ETORICOXIB 90 & 120 BIOTECH: 7 or 28 Tablets blister of Aluminium foil and CFB or PVC/PVDC or PVC/PE/PVDC foil in cardboard box.

All pack sizes and strengths may not necessarily be marketed at one time.

8. IDENTIFICATION OF ETORICOXIB BIOTECH

ETORICOXIB 60 BIOTECH: Green, round, biconvex, film-coated tablets debossed with "444" on one side and "L" on the other side.

ETORICOXIB 90 BIOTECH: White to off white, round, biconvex, film-coated tablets debossed with "445" on one side and "L" on the other side.

ETORICOXIB 120 BIOTECH: Pale-green, round, biconvex, film-coated tablets debossed with "446" on one side and "L" on the other side.

9. REGISTRATION NUMBER:

ETORICOXIB 60 BIOTECH TABLET: A.50/3.1/0586

ETORICOXIB 90 BIOTECH TABLET: A.50/3.1/0587

ETORICOXIB 120 BIOTECH TABLET: A.50/3.1/0588

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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EIENDOMSNAAM, STERKTE EN DOSEERVORM:

ETORICOXIB 60 BIOTECH TABLET
ETORICOXIB 90 BIOTECH TABLET
ETORICOXIB 120 BIOTECH TABLET

Lees die hele pamflet sorgvuldig voor jy ETORICOXIB BIOTECH begin gebruik.

- Hou hierdie pamflet. Jy mag dit weer wil lees.
- As jy verdere vrae het, bespreek dit met jou dokter of apteker.
- ETORICOXIB BIOTECH is persoonlik vir jou voorgeskryf en jy moet nie u medisyne met ander mense deel nie. Dit mag hulle benadeel, selfs as hulle simptome ooreenstem met u simptome.

1. WAT ETORICOXIB BIOTECH BEVAT

Die aktiewe bestanddeel is etoricoxib.
ETORICOXIB 60 BIOTECH TABLET
ETORICOXIB 90 BIOTECH TABLET
ETORICOXIB 120 BIOTECH TABLET

Die ander bestanddele is:

Kern:

Kalsiumfosfaat dibasies (anhidries), croscarmellose natrium, hidroksiepropielcellulose, magnesiumstearaat en mikrokristallyne sellulose.

Tabletbedekking:

Die 60 mg tablet bevat Opadry II 32K510024 Groen, saamgestel uit FD&C Blou #2 / Indigo Carmine Aluminium Lake, HPMC 2910/Hypromellose, ysteroksied geel, laktose monohidraat, titaniumdioksied en triasetien.
Die 90 mg tablet bevat Opadry II 32K580000 Wit, saamgestel uit HPMC 2910/Hypromellose, laktose monohidraat, titaniumdioksied en triasetien.
Die 120 mg tablet bevat Opadry II 32K510022 Groen, saamgestel uit FD&C Blou #2 / Indigo Carmine Aluminium Lake, HPMC 2910/Hypromellose, ysteroksied geel, laktose monohidraat, titaniumdioksied en triasetien.
ETORICOXIB BIOTECH tablette bevat suiker (laktose monohidraat): 1,68 mg per 60 mg tablet; 2,52 mg per 90 mg tablet en 3,36 mg per 120 mg tablet.

2. WAARVOOR ETORICOXIB BIOTECH GEBRUIK WORD

ETORICOXIB BIOTECH is 'n nie-steroïdale anti-inflammatoriese medisyne (NSAID) wat inflammasie, pyn en koors verlig. ETORICOXIB BIOTECH behoort aan die groep medisyne bekend as selektiewe COX-2 inhibeerders. ETORICOXIB BIOTECH word gebruik om die simptome van inflammasie (pyn en swelling) in gewigte en spiere van pasiënte met rumatoïede artritis sowel as jigsawartritis (pyn en inflammasie as gevolg van die opbou van uriensuurkristalle in gewigte) te verminder.

ETORICOXIB BIOTECH word ook gebruik vir die behandeling van:

- Ankiloserende spondylitis (n vorm van artritis wat primêr die rugstring affekteer; inflammasie van die spinale/rugstring gewigte)
- Korttermyn verligting van akute pyn (behandeling is beperk tot 'n maksimum periode van 8 dae)
- Akute pyn na tandsjirurgie
- Menstruasiepyn

3. VOORDAT JY ETORICOXIB BIOTECH BEGIN GEBRUIK

Moenie ETORICOXIB BIOTECH neem :

- as jy hipersensitief (allergies) is vir etoricoxib of enige van die ander bestanddele van ETORICOXIB BIOTECH nie.
- as jy n maagsweer het of bloei uit die maag of ingewande
- as jy ernstige lewersiekte het
- as jy ernstige niersiekte het
- as jy allergies is vir aspirien of ander nie-steroïdale anti-inflammatoriese medisyne (NSAIDs) insluitend COX-2 inhibeerders soos ETORICOXIB BIOTECH of tekens toon van allergie terwyl u hierdie medisyne gebruik soos moeilike asemhaling, loperige neus of jeuk simptome.
- as jy hoë bloeddruk het wat nie gekontroleer is nie
- as jy swanger is of borsvoed
- as jy onder die ouderdom van 16 jaar is
- as jy inflammatoriese dermsiekte het
- as jy kongestiewe hartversaking het
- as jy hartsiekte het of as jy 'n hartaanval, hartomleiding, perifere arteriële siekte (swak sirkulasie in bene of voete as gevolg van vernoude of geblokkeerde are) of as u enige tipe beroerte (insluitend mini-beroerte of verbygaande isgemiese aanvalle) gehad het
- as jy hartomleidingsjirurgie moet kry
- as jy huidiglik met litium behandel word (behandeling van bipolêre toestande)
- as jy huidiglik met digoksien behandel word (behandeling van hartversaking)

Wees spesiaal versigtig met ETORICOXIB BIOTECH:

Die gebruik van ETORICOXIB BIOTECH mag ernstige hart en sirkulatoriese toestande, gastro-intestinale toestande of velreaksies tot gevolg he wat fataal mag wees.

Praat met jou dokter of apteker voor jy ETORICOXIB BIOTECH neem as:

- jy enige geskiedenis van lewer of niersiekte het
- jy dehidrasie ervaar, byvoorbeeld as gevolg van braking of diarree.
- jy swelling ervaar as gevolg van vloeistofretensie
- jy 'n geskiedenis van hartversaking, of enige ander vorm van hartsiekte het
- jy diabetes of hoë cholesterol het, of as u rook. Jou risiko van hartkomplikasies kan verhoog word in hierdie gevalle.
- jy 'n geskiedenis van hoë bloeddruk het. ETORICOXIB BIOTECH kan bloeddruk verhoog in sommige mense, veral in hoë dosisse, en u dokter sal u bloeddruk van tyd tot tyd wil monitor.
- jy 'n geskiedenis het van enige medisyne allergie. Jy mag 'n hoër risiko vir ernstige velreaksies hê.
- jy 'n geskiedenis het van maagbloeding of swere.
- jy behandel word vir 'n infeksie. ETORICOXIB BIOTECH kan 'n koors maskeer of verberg, wat 'n teken is van infeksie.
- jy 'n vrou is wat probeer swanger word.
- jy oor die ouderdom van 65 jaar is.
- jy op warfarin of enige ander anti-koagulant behandel is. Jou dokter sal jou bloeityd monitor. As jy enige hipersensitiwiteit (allergiese) reaksie toon met aspirien, moet jy behandeling met ETORICOXIB BIOTECH vermy.

Inname van ETORICOXIB BIOTECH met kos en vloeistof: ETORICOXIB BIOTECH mag geneem word met of na maaltye.

Swangerskap en borsvoeding:

Indien jy swanger is of borsvoed, konsulteer asseblief jou dokter, apteker of ander gesondheidsorgwerker vir advies voordat u ETORICOXIB BIOTECH neem. ETORICOXIB BIOTECH moet nie gedurende swangerskap geneem word nie, of as jy borsvoed nie.

Bestuur en gebruik van masjinerie:

Jy mag duiseligheid of lomerigheid/slaperigheid ervaar tydens gebruik van ETORICOXIB BIOTECH. Moenie masjinerie bestuur of hanteer as u duiseligheid of lomerigheid ervaar nie.

Belangrike informasie oor sommige van die bestanddele van ETORICOXIB BIOTECH:

ETORICOXIB BIOTECH bevat laktose (melksuiker). Indien jy weet dat jy nie laktose kan verteer en metaboliseer nie (laktose intoleransie), lig jou dokter in voor jy ETORICOXIB BIOTECH gebruik.

Die gebruik van ander medisyne saam met ETORICOXIB BIOTECH:

Lig altyd jou gesondheidsorgwerker indien u enige ander medikasie gebruik. (Dit sluit komplementêre of tradisionele medisyne in.)

Indien jy enige van die volgende medisyne neem, mag jou dokter u medikasie wil aanpas sodra jy ETORICOXIB BIOTECH begin gebruik:

- siklosporien of takrolimus (medikasie wat die immunsisteem onderdruk)
- medisyne wat jou bloed verdun (anti-koagulant), soos warfarin.
- Rifampicin ('n antibiotika)
- metotreksaat ('n medisyne wat gebruik word om die immunsisteem te onderdruk, en gereeld gebruik word vir behandeling van rumatoïede artritis)
- diuretika (watertablette)
- medisyne wat hoë bloeddruk en hartversaking help kontroleer, wat ACE inhibeerders en angiotensien reseptorblokkeerders genoem word, soos enalapril en ramipril, asook losartan en valsartan.
- litium ('n medisyne wat gebruik word om sekere tipes depressie te behandel)
- geboorte kontroleer tablette (die kombinasie mag jou risiko vir nuwe-effekte verhoog)
- hormoonvervangings terapie (die kombinasie mag jou risiko vir nuwe-effekte verhoog)
- digoksien ('n medisyne vir hartversaking en onreëlmatige hartritme)
- minoksidil ('n medisyne wat gebruik word om hoë bloeddruk te behandel)
- salbutamol tablette of oplossing ('n medisyne vir asma)
- aspirien, die risiko vir maagswere is groter as jy ETORICOXIB BIOTECH gebruik saam met aspirien.

Aspirien vir die voorkoming van hartaanvalle of beroerte: ETORICOXIB BIOTECH kan geneem word saam met lae dosering aspirien. Indien jy huidiglik lae dosis aspirien gebruik om hartaanvalle of beroerte te verhoed, moet jy nie die aspirien staak voordat jy met jou dokter gepraat het nie.

Aspirien en ander non-steroïdale anti-inflammatoriese medisyne (NSAIDs):

Moet nie hoë dosis aspirien of ander anti-inflammatoriese medisyne neem tydens die gebruik van ETORICOXIB BIOTECH nie.

4. HOE OM ETORICOXIB BIOTECH TE NEEM

Moet nie medisyne wat vir jou voorgeskryf is met ander persone deel nie. Neem ETORICOXIB BIOTECH altyd soos jou dokter dit voorgeskryf het. Jy behoort met jou dokter of apteker te bevestig as jy onseker is. ETORICOXIB BIOTECH word mondelings (oraal) geneem. ETORICOXIB BIOTECH mag met of sonder voedsel geneem word. Gebruik die laagste effektiewe dosis vir die kortste tydperk.

Rumatoïede Artritis:

Die aanbevole dosis is 90 mg een keer per dag. In sommige pasiënte mag 60 mg een keer per dag genoegsame terapeutiese voordeel verskaf. Die dosis vir rumatoïede artritis moet nie 90 mg daaglik oorskry nie.

Ankiloserende Spondylitis (inflammasie van die spinale gewigte):

Die aanbevole dosis is 90 mg een keer per dag. Die dosis vir ankiloserende spondylitis moet nie 90 mg daaglik oorskry nie.

Korttermyn verligting van akute pyn:

Die aanbevole dosis is 90 mg een keer per dag, beperk tot 'n maksimum van 8 dae behandeling. Die dosis vir akute pyn moet nie 120 mg daaglik oorskry nie.

Akute jigsawartritis:

Die aanbevole dosis is 120 mg een keer per dag. ETORICOXIB BIOTECH behoort net vir die akute simptomaties periode gebruik te word, beperk tot 'n maksimum van 8 dae behandeling. Die dosis vir akute pyn moet nie 120 mg daaglik oorskry nie.

Menstruele pyn:

Die aanbevole dosis is 120 mg een keer per dag. Die dosis vir primêre dismenoree moet nie 120 mg daaglik oorskry nie.

Akute pyn na tandsjirurgie:

Die aanbevole dosis is 90 mg een keer per dag. Die dosis vir post-operatiewe tandsjirurgie pyn moet nie 90 mg oorskry nie.

Gebruik in kinders en adolessente:

ETORICOXIB BIOTECH tablette moet nie deur kinders of adolessente onder die ouderdom van 16 jaar gebruik word nie.

Bejaarde pasiënte:

Geen aanpassing van dosering is nodig vir bejaarde pasiënte nie, alhoewel bejaarde mense meer geneig mag wees om nuwe-effekte te ervaar. Jou dokter sal jou meer intensief monitor as jy 'n bejaarde is met nier-, lewer- of hartsdisfunksie.

Pasiënte met lewerprobleme:

As jy ligte lewersiekte het, moet jy nie meer as 60 mg per dag neem nie.
As jy matige lewersiekte het, moet jy nie meer as 60 mg elke tweede dag neem nie
Jou dokter sal jou inlig hoe lank jou behandeling met ETORICOXIB BIOTECH sal duur.
As jy die indruk het dat die effek van ETORICOXIB BIOTECH te sterk of te swak is, bespreek dit met jou dokter of apteker.

As jy meer ETORICOXIB BIOTECH inneem as wat jy moet:

In die geval van 'n oordosis, konsulteer jou dokter of apteker. Indien beide nie beskikbaar is nie, kontak die naaste hospitaal of vergiftigingsentrum.

As jy vergeet om 'n dosis ETORICOXIB BIOTECH te neem:

As jy vergeet het om 'n dosis te neem, moet jy die normale skedule volg die volgende dag. Moet nie 'n dubbele dosis neem om te vergoed vir die individuele doserings wat oorgeslaan is nie.

5. MOONTLIKE NUWE-EFFEKTE

ETORICOXIB BIOTECH kan nuwe-effekte hê. Nie alle nuwe-effekte gerapporteer vir ETORICOXIB BIOTECH is ingesluit in hierdie pamflet nie. Indien jou algemene gesondheid versleg of as jy enige ongewenste effek ervaar tydens behandeling met ETORICOXIB BIOTECH, konsulteer asseblief jou dokter, apteker of gesondheidsorgwerker vir advies.

As enige van die volgende gebeur, staak die gebruik van ETORICOXIB BIOTECH en lig jou dokter onmiddellik in of gaan na die ongevalle departement van jou naaste hospitaal

- kortasem, borskaspyn, of geswelde enkels wat lyk of dit erger word
 - vertingeling van die vel en oë, ook bekend as geelsug – hierdie simptome is tekens van lewerprobleme
 - erge of aanhoudende maagpyn of jou stoelgang wat swart word
 - 'n allergiese reaksie - swelling van die gesig, lippe, tong of keel, wat dit mag moeilik maak om te sluk of asem te haal.
 - Velprobleme soos swere of blases
- Hierdie is alles baie ernstige nuwe effekte. As jy hierdie nuwe-effekte ervaar, mag jy 'n baie ernstige reaksie teen ETORICOXIB BIOTECH gehad het. Jy mag dringende mediese aandag of hospitalisasie benodig.

Lig jou dokter onmiddellik in of gaan na die ongevalle afdeling van naaste hospitaal as jy enige van die volgende sien:

- ongereelde hartritme (disritmia), vinnige of ongereelde hartspoed, erge verhoging van bloeddruk
 - abnormale hartritme (atriale fibrilasie), hartversaking, 'n gevoel van styfheid, drukkings of 'n swaar gevoel in die borskas (angina pectoris), hartaanval, bloesing, beroerte of mini-beroerte (verbygaande isgemiese aanval)
 - vermindering van die aantal rooibloedselle, vermindering van die aantal witbloedselle, vermindering van die aantal bloedselle.
 - Anemie (as gevolg van gastro-intestinale bloeding)
- Hierdie is almal ernstige nuwe effekte. Jy mag dringende mediese aandag benodig.

Die volgende nuwe-effekte kan voorkom gedurende behandeling met ETORICOXIB BIOTECH:

Gereelde nuwe effekte:

- droë tandholte (inflammasie en pyn na tand-ekstrasie)
- swelling van die bene en/of voete as gevolg van vloeistofretensie (edeem)
- duiseligheid, hoofpyn
- verhoogde bloeddruk
- maagpyn, winderigheid (oormatige gas), sooibrand, diarree, swak spysvertering (dyspepsie), ongemak in die maag, naarheid
- kneusing
- swakheid en moegheid, griepagtige simptome
- verandering in bloettoets wat verband hou met jou lewer

Minder gereelde nuwe effekte:

- gastro-enteritis (inflammasie van die gastro-intestinale kanaal wat beide die maag en dunderm insluit (maaggriep), boonste lugweg infeksie, urienweg infeksie.
- toename of vermindering van eetlust, gewigstoename
- angstigheid, depressie, afname in geestelike skerpheid/fokus.
- onvermoë om te slaap, verlies van gevoel of tinteling.
- oog-irritasie en rooiheid
- suising van die ore, vertigo (spinsensasie terwyl in 'n onbeweeglike posisie)
- inflammasie van die bloedvate
- hoes, uitasemheid, neusbloeding
- opgeblaasheid van maag of derm, suur-refluks, verandering van jou dermbeweging, konstipasie, gastritis (inflammasie van die maagvoering), naarheid (braking)
- droë mond, maagsweer, prikkelbare dermsindroom, inflammasie van die pankreas
- inflammasie van die slukderm, mondsere
- swelling van die gesig, uitslag of jeuk van die vel, rooiheid van die vel
- spierkrampe/spasma, spierpyn/styfheid
- hoë vlakke van kalium in jou bloed, verandering in bloed- of urientoets wat verband hou met jou niere, ernstige nierprobleme
- lae vlakke van natrium

Die frekwensie van die volgende nuwe-effekte is nie bekend nie:

- hipersensitiwiteit ('n allergiese reaksie wat opgehewe knoppe veroorsaak wat ernstig genoeg mag wees om onmiddellike mediese aandag te vereis)
- verwarring, rusteloosheid
- die voel of hoor van dinge wat nie daar is nie (hallusinasies)
- smaakverandering, lomerigheid
- versteurde visie
- inflammasie van die maagvoering wat ernstig kan word en mag lei tot bloeding
- ernstige velreaksies

As jy enige nuwe-effekte ervaar wat nie in hierdie pamflet genoem word nie, stel asseblief jou dokter of apteker in kennis.

6. BEWARING EN WEGDOENING VAN WEGDOENING VAN ETORICOXIB BIOTECH

Bewaar teen of benede 30 °C.
Bêre die medikasie in die oorspronklike verpakking. Beskerm teen vog.

Hou stulpverpakings in karton totdat dit nodig is vir gebruik.

Hou alle medisyne buite bereik van kinders. Neem alle ongebruikte medisyne terug na jou apteker. Moet nie ongebruikte medisyne in afvoerpyne of rioleringsisteme (bv. toilette) weggooi nie.

7. AANBIEDING VAN ETORICOXIB BIOTECH

ETORICOXIB BIOTECH word verpak as volg:
• ETORICOXIB 60 BIOTECH: 28 Tablette in 'n stulpverpakking van Aluminium foelie en CFB of PVC/PVDC of PVC/PE/PVDC foelie in 'n karton.
• ETORICOXIB 90 & 120 BIOTECH: 7 or 28 Tablette in 'n stulpverpakking van Aluminium foelie en CFB of PVC/PVDC of PVC/PE/PVDC foelie in 'n karton.

Al die verpakingsgroottes en sterktes word nie noodwendig op een slag bemark nie.

8. DENTIFIKASIE VAN ETORICOXIB BIOTECH

ETORICOXIB 60 BIOTECH: Groen, ronde, bikonvekse, filmbedekte tablette relifbedruk met "444" aan die een kant en "L" aan die ander kant.
ETORICOXIB 90 BIOTECH: Wit tot afwit, ronde, bikonvekse, filmbedekte tablette relifbedruk met "445" aan die een kant en "L" aan die ander kant.
ETORICOXIB 120 BIOTECH: Liggroen, ronde, bikonvekse, filmbedekte tablette relifbedruk met "446" aan die een kant en "L" aan die ander kant.

9. REGISTRASIE NOMMER

ETORICOXIB 60 BIOTECH TABLET: 50/3.1/0586
ETORICOXIB 90 BIOTECH TABLET: 50/3.1/0587
ETORICOXIB 120 BIOTECH TABLET: 50/3.1/0588

10. NAAM EN ADRES VAN REGISTRASIE HOUER

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11. DATUM VAN PUBLIKASIE

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