

Proprietary Name:

Etoricoxib 60 Biotech & Etoricoxib  
90 Biotech & Etoricoxib 120 Biotech

Dosage Form &amp; Strength:

Tablets: Each film-coated tablet  
contains 60, 90 or 120 mg etoricoxib,  
respectively.Submitted: 31 August 2021, approved  
06 Dec 2021**PATIENT INFORMATION LEAFLET****SCHEDULING STATUS:**

S3

**ETORICOXIB 60 BIOTECH, 60 mg etoricoxib film-coated tablets****ETORICOXIB 90 BIOTECH, 90 mg etoricoxib film-coated tablets****ETORICOXIB 120 BIOTECH, 120 mg etoricoxib film-coated tablets****Etoricoxib**

**Contains 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.**

**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, pharmacist, nurse or other healthcare provider.
- 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.

**What is in this leaflet**

1. What ETORICOXIB BIOTECH is and what it is used for
2. What you need to know before you take ETORICOXIB BIOTECH
3. How to take ETORICOXIB BIOTECH
4. Possible side effects
5. How to store ETORICOXIB BIOTECH
6. Contents of the pack and other information

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## 1. What ETORICOXIB BIOTECH is and what it 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

## 2. What you need to know 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 (listed in section 6).
- 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

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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)

### Warnings and precautions

#### 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.

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- 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.
  - You develop flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).

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

### **Other medicines and ETORICOXIB BIOTECH**

Always tell your healthcare provider if you are taking any other medicine. (This includes all 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

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- 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.

### **ETORICOXIB BIOTECH with food and drink**

ETORICOXIB BIOTECH may be taken with or after food.

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult

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your doctor, pharmacist or other healthcare provider for advice before taking ETORICOXIB BIOTECH.

ETORICOXIB BIOTECH should not be taken during pregnancy or if you are breastfeeding your baby.

### **Driving and using machines**

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

It is not always possible to predict to what extent ETORICOXIB BIOTECH may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ETORICOXIB BIOTECH affects them.

### **ETORICOXIB BIOTECH contains lactose monohydrate**

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

### **3. 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 told you. Check with your doctor or pharmacist if you are not sure.

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.

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06 Dec 2021*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.

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### 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 overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

### If you forget to take 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.

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#### 4. 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 provider 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

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- anaemia (as a result of gastrointestinal bleeding)
  - flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).

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

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- 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

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

### Reporting of 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 ETORICOXIB BIOTECH.

## 5. How to store ETORICOXIB BIOTECH

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in the original package.

Protect from moisture.

Keep blisters in outer carton until required for use.

Return all unused medicine to your pharmacist.

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

## 6. Contents of the pack and other information

### 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.

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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.

### **What ETORICOXIB BIOTECH looks like and contents of the pack**

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.

ETORICOXIB BIOTECH are packed as follow:

Applicant/ PHCR

Biotech Laboratories (Pty) Ltd.

Patient Information Leaflet

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- 8 Tablets Blister of Unprinted Aluminium Foil and Unprinted CFB foil in cardboard box;
- 10 Tablets Blister of Unprinted Aluminium Foil and PVC/PVDC foil in cardboard box;
- 10 Tablets Blister of Unprinted Aluminium Foil and PVC/PE/PVDC foil in cardboard box.

### **Holder of Certificate of Registration**

Biotech Pharmaceuticals (Pty) Ltd.

Block K West, Central Park

400 16<sup>th</sup> Road, Randjespark

Midrand

1685

Tel No.: +27 (0) 11 848 3050

### **This leaflet was last revised in**

31 August 2021, SAHPRA approval – 06 December 2021

### **Registration number**

ETORICOXIB 60 BIOTECH: 50/3.1/0586

ETORICOXIB 90 BIOTECH: 50/3.1/0587

ETORICOXIB 120 BIOTECH: 50/3.1/0588