

BIOCOXIB 90MG/120MG FILM COATED TABLET

Etoricoxib (90mg, 120mg)

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What **BIOCOXIB** is used for

Your doctor has prescribed **BIOCOXIB** Tablet for:

- treatment of osteoarthritis
- treatment of rheumatoid arthritis
- treatment of ankylosing spondylitis
- treatment of acute pain after minor dental procedures
- treatment of menstrual pain
- treatment of gout attacks

Osteoarthritis is a joint disease. It results from the gradual breakdown of the cartilage that cushions the ends of the bones, resulting in pain, inflammation, tenderness, stiffness, and physical disability.

Rheumatoid arthritis is a chronic disease that causes pain, stiffness, swelling and loss of function in the joints and inflammation in other body organs.

Ankylosing spondylitis is an inflammatory disease of the spine and large joints.

Gout is a disorder characterized by sudden, recurring attacks of pain and inflammation in one or more joints.

You may obtain further information from your doctor or pharmacist, who have more detailed information.

How **BIOCOXIB** works

Etoricoxib is a non-steroidal anti-inflammatory drug (NSAIDs) which is highly selective cyclo-oxygenase-2 (COX-2) inhibitor with anti-inflammatory and analgesic properties.

Before you use **BIOCOXIB**

- When you must not use it

Do not use **BIOCOXIB**:

- If you are allergic to Etoricoxib or any of the others ingredients
- If you are allergic to NSAIDs, including aspirin and COX-2 inhibitors
- If you have stomach ulcer
- If you have serious liver disease
- If you have serious kidney disease
- If you are under 16 years' old
- If you have inflammatory bowel disease
- If you have high blood pressure that has not been control by treatment
- If you have heart problems including heart failure, angina (chest pain), heart attack, bypass surgery or peripheral arterial disease (poor circulation in legs or feet due to narrow or blocked arteries)
- If you have any kind of stroke

Pregnancy and lactation

BIOCOXIB must not be used during pregnancy. Consult your doctor if you need more advices.

BIOCOXIB should be used with caution during breast-feeding. Consult your doctor before taking this medicine.

- Before you start to use it

Check with your doctor or pharmacist before taking **BIOCOXIB** if:

- you have allergies to any other medicines
- you have health problems or any other medical conditions.

- Taking other medicines

Please tell your doctor or pharmacist if you are using or have recently used any following medicines:

- Angiotensin Converting Enzyme (ACE) Inhibitors and Angiotensin II Antagonists (AIAs) (used to control blood pressure)
- Azole antifungals e.g. Fluconazole, Ketoconazole (used to treat fungal infections of the body and skin)
- Corticosteroid oral e.g. Prednisolone (used to provide relief for inflamed areas)
- Anticoagulant e.g. Warfarin (to slow down blood clotting)
- Cyclosporine and tacrolimus (used in the treatment of immune-mediated diseases)
- Diuretics (to increase the amount of water and salt expelled from the body as urine)
- Lithium (used to treat bipolar disorder)
- Methotrexate (used to suppress the immune system and rheumatoid arthritis)
- Acetylsalicylic acid (used to reduce pain, fever or inflammation)
- Oral contraceptives
- Hormone Replacement Therapy
- Digoxin (used to control some heart problems)

How to use **BIOCOXIB**

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, consult your doctor or pharmacist.

BIOCOXIB should be administered for the shortest duration possible and the lowest effective daily dose should be used.

For treatment of osteoarthritis:

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

For treatment of rheumatoid arthritis:

- The recommended dose is 60 mg once a day, and may increase to 90 mg once a day if needed.

For treatment of ankylosing spondylitis:

- The recommended dose is 60 mg once a day, and may increase to 90 mg once a day if needed.

Acute pain conditions:

The recommended dose is 90mg or 120mg once daily. BIOCOSIB should be used only for the acute period limited to a maximum of 8 days.

For the relief of gout attacks and the treatment of menstrual pain:

- The recommended dose is 120 mg once a day which should only be used for the acute painful period.

For the relief of pain after minor dental procedures

- The recommended dose is 90mg once a day.

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

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

- When to use it

BIOCOSIB may be taken with or without food. Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking BIOCOSIB for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your

next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much tablet may cause gastrointestinal, heart and kidneys disorders.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that you are taking BIOCOSIB.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give BIOCOSIB to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines:

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, BIOCOSIB can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any following side effects after taking this medicine (including any side effects that not on this list).

Common:

- Painful dental condition after permanent adult tooth extracted
- fluid retention
- dizziness, headache
- feeling of fast heartbeat, problem of heartbeat rate
- High blood pressure
- muscles in the lungs tighten, causing restricted airflow
- Constipation, flatulence, gastritis, heartburn/acid reflux, diarrhea, dyspepsia/epigastric discomfort, nausea, vomiting, inflammation of the esophagus, oral ulcer
- Increase in AST and ALT levels
- Small bruise caused by blood leaking from broken blood vessels into the tissue of the skin
- asthenia/fatigue, flu-like disease

Serious:

- Toxicity in the kidneys including interstitial nephritis (kidney tubules become swollen) and nephrotic syndrome (damage to your kidneys causes these organs to release too much protein into your urine)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of BIOCOSIB

- Storage

Store below 30 °C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

BIOCOXIB (90 mg) is asymmetric hexagonal with rounded corners, white film-coated tablet, impressed “BC” on one side and “90” on the other.

BIOCOXIB (120 mg) is asymmetric

hexagonal with rounded corners, light green film-coated tablet, impressed “BC” on one side and “120” on the other.

- Ingredients

- Active ingredient
Etoricoxib

- Inactive ingredients
BIOCOXIB 90 mg
Microcrystalline Cellulose
Dibasic Calcium Phosphate
Croscarmellose Sodium
Magnesium Stearate
Hypromellose
Polyethylene Glycol
Titanium Dioxide
Carnauba Wax
Purified Water

BIOCOXIB 120 mg

Microcrystalline Cellulose
Dibasic Calcium Phosphate
Croscarmellose Sodium
Magnesium Stearate
Hypromellose
Polyethylene Glycol
Brilliant Blue Lake
Iron Oxide Yellow
Titanium Dioxide
Carnauba Wax
Purified Water
Isopropyl alcohol

- MAL number:

BIOCOXIB 90 mg Film Coated Tablet

MAL*****

BIOCOXIB 120 mg Film Coated Tablet

MAL*****

Product Registration Holder

Medispec (M) Sdn Bhd
No 55&57, Lorong Sempadan 2,
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Date of revision

19/05/2021

Serial number

NPRA (R2) 20/119

Manufacturer

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