

BIOWELL BREAMORE

Montelukast Chewable Tablet 5mg

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What BioWell Breamore is used for

Your doctor has prescribed BioWell Breamore (montelukast sodium) to treat:

- Asthma, including preventing your asthma symptoms during the day and night. BioWell Breamore also prevents the narrowing of airways triggered by exercise.
- Allergic rhinitis (seasonal and perennial), including daytime and nighttime symptoms: nasal congestion, runny nose, nasal itching, and sneezing; nasal congestion upon awakening, difficulty going to sleep, and nighttime awakenings; tearing, itchy, red, and puffy eyes.

What is asthma?

Asthma is a chronic lung disease. It cannot be cured – only controlled.

Characteristics of asthma include:

- Narrowed airways causing breathing to become difficult. This narrowing worsens and improves in response to various conditions.
- Inflamed airways; that is, the lining of airways become swollen.
- Sensitive airways that react to many things, such as cigarette smoke, pollen, or cold air.

Symptoms of asthma include:

Coughing, wheezing and chest tightness. Not all people with asthma wheeze. For some, coughing may be

the only symptom of asthma. Symptoms often occur during the night or after exercise.

What is exercise-induced asthma?

Exercise-induced asthma, more accurately called exercise-induced bronchoconstriction (EIB) occurs when exercise triggers symptoms of asthma.

How do I know if I have asthma?

Your doctor will determine if you have asthma based on your symptoms and/or on how well you are able to move air out of your lungs. Your doctor may use a device called a peak flow meter or a spirometer to test your lung function.

Treatment can control asthma. It is important to treat even mild symptoms of asthma so that you can prevent them from getting worse.

How should asthma be treated?

To help prevent asthma symptoms and improve your breathing you will have to work closely with your doctor to: Plan ways to avoid or reduce contact with conditions that may trigger an asthma episode (for example, smoking including second-hand smoke, house dust mites, cockroaches, molds, pollen, animal dander, changes in weather and temperature, and infections in the upper airway (such as colds)). Develop a treatment plan that best controls your asthma.

Why is compliance (taking my medicine as prescribed) important?

Taking your medicine as your doctor or health care provider instructs may. Help reduce the severity of your asthma and the frequency of your asthma attacks.

What is allergic rhinitis?

- Seasonal allergic rhinitis (also known as hay fever) is triggered by outdoor allergens such as airborne pollens from trees, grasses, and weeds.
- Perennial allergic rhinitis may occur year-round and is generally triggered by indoor allergens such

as dust mites, animal dander, and/or mold spores.

- The daytime and nighttime symptoms of allergic rhinitis typically may include:
 - Stuffiness, runny, itchy nose
 - Sneezing
 - Watery, swollen, red, itchy eyes

How BioWell Breamore works

This medicine is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in your lungs. Blocking leukotrienes improves asthma symptoms and helps prevent asthma attacks. Leukotrienes also cause allergy symptoms. Blocking leukotrienes improves allergic rhinitis (seasonal and perennial, also known as outdoor and indoor nasal allergies).

Before you use BioWell Breamore

- When you must not use it

Do not take BioWell Breamore if you or your child:

- are allergic to any of its component

- Before you start to use it

Tell your doctor (or health care provider) about any medical problems or allergies you or your child has now or has had.

Studies have shown that Montelukast sodium does not affect the growth rate of children.

Safety and effectiveness of BioWell Breamore in children less than 12 months old have not been established.

Use in pregnancy

Women who are pregnant or intend to become pregnant should consult their doctor before taking BioWell Breamore.

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Use in breast-feeding

It is not known if BioWell Breamore appears in breast milk. You should consult your doctor before taking BioWell Breamore if you are breast-feeding or intend to breast-feed.

- Taking other medicines

In general, BioWell Breamore does not interfere with other medicines that you or your child may be taking. However, some medicines may affect how BioWell Breamore works, or BioWell Breamore may affect how your other medicines work. It is important to tell your doctor about all medicines that you or your child is using or plan to use, including those obtained without a prescription.

Can I drive or operate machinery while using BioWell Breamore?

BioWell Breamore is not expected to affect your ability to drive a car or operate a machinery.

How to use BioWell Breamore

Take BioWell Breamore once a day with or without food, as your doctor has prescribed.

- How much to use

The dose for children 6 to 14 years old for the treatment of asthma and/or allergic rhinitis is one 5-mg chewable tablet daily.

- When to use it

For patients with asthma, take BioWell Breamore once a day in the evening.

For patients with allergic rhinitis, take BioWell Breamore once a day as prescribed by your doctor.

- How long to use it

It is important to continue taking BioWell Breamore for as long as your doctor prescribes it in order to maintain control of your or your child's asthma. BioWell Breamore can treat your or your child's asthma only if you or your child continues to take it.

- If you forget to use it

Try to take BioWell Breamore as prescribed. However, if you or your child misses a dose, just resume the usual schedule of one tablet daily.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, 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.

While you are using BioWell Breamore

- Things you must do

It is important that you or your child continue taking BioWell Breamore daily as prescribed by your doctor, even when you or your child has no symptoms or if you or your child had an asthma attack.

If you or your child's asthma symptoms get worse, you should contact your doctor immediately.

BioWell Breamore is not for treatment of acute asthma attacks. If an attack occurs, you or your child should follow the instructions your doctor has given you for that situation.

Behavior and mood-related changes have been reported in patients taking Montelukast Sodium. If you or your child experience these changes while taking BioWell Breamore (see "Side effects"), tell your doctor.

- Things you must not do

If you have been prescribed the 10 mg tablets, do not take two 5 mg chewable tablets in its place. If you have been prescribed the 5 mg chewable tablets, do not take half a 10 mg in its place.

The different strength tablets may not have the same effect, as they are absorbed slightly differently in the body.

Do not take BioWell Breamore to relieve an acute asthma attack. In

case of an acute asthma attack, follow your doctor's instructions on what reliever medicine to use.

Remember that your doctor has prescribed this medicine only for you or your child. Never give it to anyone else.

- Things to be careful of

Take notice:

- if your condition's symptoms become worse, contact your doctor immediately
- not to replace this medicine with other medicine to treat asthma prescribed by your doctor
- not to take aspirin or non-steroidal anti-inflammatory medicine if it makes your asthma worse

Side effects

Any medicines may have unintended effects, so-called side effects. BioWell Breamore is generally well-tolerated. In studies, the most common side effects reported were abdominal pain, headache, thirst, diarrhea, hyperactivity, asthma, scaly and itchy skin, and rash. These were usually mild and occurred as often in patients treated with BioWell Breamore or placebo (a pill containing no medication).

Additionally, the following have been reported:

- upper respiratory infection
- increased bleeding tendency, low blood platelet count
- allergic reactions [including swelling of the face, lips, tongue, and/or throat (which may cause trouble breathing or swallowing), hives, rash and itching]
- behavior and mood related changes [agitation including aggressive behavior or hostility, depression, disorientation, disturbance in attention, dream abnormalities, feeling anxious, hallucinations, insomnia, irritability, memory impairment, obsessive-compulsive symptoms, restlessness, sleep walking, stuttering, suicidal

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- thoughts and actions, tremor, uncontrolled muscle movements]
- dizziness, drowsiness, pins and needle/numbness, very rarely seizure
 - palpitations
 - nose bleed; swelling (inflammation) of the lungs
 - diarrhea, dyspepsia, nausea, vomiting
 - hepatitis
 - bruising, severe skin reactions (erythema multiforme) that may occur without warning
 - joint pain, muscle aches and muscle cramps
 - bedwetting in children
 - weakness/ tiredness
 - swelling
 - fever

Tell your healthcare provide right away if you notice any of the following behavior and mood related changes: Obsessive-compulsive symptoms.

Tell your doctor or pharmacist if you or your child develops any unusual symptom, or if any known symptom continues or worsens.

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)]

How can I learn more about BioWell Breamore and the condition for which it was prescribed?

You may obtain further information from your physician or pharmacist, who have more detailed information about BioWell Breamore and your condition.

Storage and Disposal of BioWell Breamore

- Storage

Keep out of reach of children.

Store below 30⁰C. Protect from light and moisture.

- 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

10 mm, round, pink mottled uncoated tablet, bevel-edged, shallow convex faces, “HD” embossed and scored on the same face.

- Ingredients

- Active ingredients
Montelukast Sodium 5mg.

- Inactive ingredients
Mannitol
Microcrystalline cellulose
Red iron oxide
Croscarmellose sodium
Cherry flavor
Sucralose
Magnesium Stearate

- MAL Number:
MAL20XXXXXXAZ

Manufacturer

HOVID BERHAD
Lot 56442, 7 ½ Miles Jalan
Ipoh/Chemor,
31200, Chemor, Perak, Malaysia.

Product Registration Holder

Hovid Nutriworld Sdn. Bhd.
121, Jalan Tunku Abdul Rahman,
30010 Ipoh, Perak.

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19/11/2024

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