

BILAXTEN 10mg Orodispersible Tablets

Bilastine

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What Bilaxten is used for

Bilaxten is used to relieve the symptoms of hayfever (sneezing, itchy, runny, blocked-up nose and red and watery eyes) and other forms of allergic rhinitis. It may also be used to treat itchy skin rashes (hives or urticaria).

How Bilaxten works

Bilaxten contains the active substance bilastine which is an antihistamine. Bilastine is a non-drowsy, long-acting antihistamine that helps to relieve symptoms of allergy such as sneezing, tearing and itching. It blocks the effects of histamine, a chemical substance produced by the body in response to foreign substances which the body is allergic to.

Before you use Bilaxten

- When you must not use it

If your child is allergic to bilastine or any of the other ingredients of this medicine.

- Before you start to use it

Do not give this medicine to children under 6 years of age with a body weight below 20 kg since no sufficient data are available.

Talk to your doctor or pharmacist before using Bilaxten if your child has moderate or severe renal or

hepatic impairment or if your child is taking other medicines.

- Taking other medicines

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines, including medicines obtained without a prescription. Some medicines should not be taken together and others may need their doses to be altered when taken together.

Always inform your doctor or pharmacist if your child is using or receiving any of the following medicines in addition to Bilaxten.

- Ketoconazole (an antifungal medicine)
- Erythromycin (an antibiotic)
- Diltiazem (to treat angina)
- Cyclosporine (to reduce the activity of your immune system, thus avoiding transplant rejection or reducing disease activity in autoimmune and allergic disorders, such as psoriasis, atopic dermatitis or rheumatoid arthritis)
- Ritonavir (to treat AIDS)
- Rifampicin (an antibiotic)

How to use Bilaxten

- How much to use

Bilaxten 10 mg orodispersible tablets are indicated in children aged 6 to 11 years with a body weight of at least 20 kg.

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Children

The recommended dose in children 6 to 11 years of age with a body weight of at least 20 kg is 10 mg bilastine (1 orodispersible tablet) once daily for the relief of symptoms of allergic rhino-conjunctivitis and urticaria.

- The orodispersible tablet is for oral use.
- Please place the orodispersible tablet in the mouth of your child. It will disperse rapidly in saliva and can then be easily swallowed.
- Alternatively, you may disperse the orodispersible tablet in a tea-spoon of water before giving it to your child. It has to be ensured that no rest of sediment remains in the spoon.
- **You should use exclusively water for dispersion**, do not use grapefruit juice or any other fruit juices.

Adults

For adults, including elderly and adolescents aged 12 years and over, the recommended dose is 20 mg bilastine once daily. For this patient population a more appropriate dosage form - tablet- is available, ask your doctor or pharmacist.

- When to use it

You should give the orodispersible tablet to your child one hour before or two hours after intake of food or fruit juice.

- How long to use it

As the duration of treatment depends on your child's underlying disease, your physician will determine for how long your child should take Bilaxten.

- If you forget to use it

If you forget to give your child the daily dose on time, give it on the same day as soon as you remember. Then, give the next dose on the next day at the usual time as prescribed by the doctor. In any case, do not give a double dose to make up for a forgotten one.

- If you use too much (overdose)

If your child, or anyone else, use too much of this medicine, tell your doctor immediately or go to the emergency department of your nearest hospital. Please remember to take this medicine pack or this leaflet with you.

While you are using it

- Things you must do

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Things you must not do

Do not use if your child is allergic to bilastine or any of the other ingredients of this medicine.

Do not give this medicine to children under 6 years of age with a body weight below 20 kg since no sufficient data are available.

- Things to be careful of

Bilaxten with food, drink and alcohol

The orodispersible tablet should **not** be taken with **food or with grapefruit juice or other fruit juices**, as this will decrease the effect of bilastine. To avoid this, you can:

- give your child the orodispersible tablet and wait for one hour before your child takes food or fruit juice or
- if your child has taken food or fruit juice, wait for two hours before giving him the oral dispersible tablet.

Bilaxten, at the dose recommended in adults (20 mg), does not increase the drowsiness produced by alcohol.

Pregnancy, breast-feeding and fertility

This medicine is for use in children from 6 to 11 years of age with a body weight of at least 20 kg. However, following information should be noted regarding the safe use of this medicine. There are no or limited amount of data from the use of bilastine in pregnant women and

during breast-feeding and on the effects on fertility.

In case of pregnancy or breast-feeding, or when planning to have a baby, it is recommended to ask to the doctor for advice before taking this medicine. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

It has been demonstrated that bilastine 20 mg does not affect the driving performance in adults. However the response from each patient to the medicine may be different. Therefore you should check how this medicine affects your child, before you let your child ride bicycles or drive other vehicles or operate machinery.

Side effects

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

Side effects that may be experienced in children are:

Common: may affect up to 1 in 10 people

- rhinitis (nasal irritation)
- allergic conjunctivitis (red and itchy eyes)
- headache
- stomach pain (abdominal/upper abdominal pain)

Uncommon: may affect up to 1 in 100 people

- eye irritation
- dizziness
- loss of consciousness
- diarrhoea
- nausea (the feeling of being sick)
- lip swelling
- eczema
- urticaria (hives)
- fatigue

Side effects that may be experienced in adults and adolescents are:

Common: may affect up to 1 in 10 people

- headache
- drowsiness

Uncommon: may affect up to 1 in 100 people

- abnormal ECG heart tracing
- blood tests which show changes in the way the liver is working
- dizziness
- stomach pain (abdominal/ upper abdominal pain)
- tiredness
- increased appetite
- irregular heartbeat
- increased weight
- nausea (the feeling of being sick)
- anxiety
- dry or uncomfortable nose
- stomach discomfort
- diarrhoea
- gastritis (inflammation of the stomach wall)
- vertigo (a feeling of dizziness or spinning)
- feeling of weakness
- thirst
- dyspnoea (difficulty in breathing)
- dry mouth
- indigestion
- itching
- cold sores (oral herpes)
- fever
- tinnitus (ringing in the ears)
- difficulty in sleeping
- blood tests which show changes in the way kidney is working
- blood fats increased

Frequency not known: cannot be estimated from the available data

- palpitations (feeling your heart beat)
- tachycardia (fast heart beat)
- Allergic reactions the signs of which may include difficulty in breathing, dizziness, collapsing or losing consciousness, swelling of your face, lips, tongue or throat, and/or swelling and redness of the skin. If you notice any of these serious side effects, stop taking the medicine and

seek urgent medical advice straight away

- Vomiting

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 (Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines(AEFI)]”.

Storage and Disposal of Bilaxten

- Storage

Store below 30 °C

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Bilaxten orodispersible tablets are round, slightly biconvex, white, of 8 mm diameter.

- Ingredients

-Active ingredient(s):

Each orodispersible tablet contains 10 mg of bilastine.

-Inactive ingredients:

mannitol, croscarmellose sodium, sodium stearyl fumarate, sucralose, red grape flavour (major components: gum arabic, ethyl butyrate, triacetin, methyl anthranilate, ethyl propionate, ethyl acetate, ethanol, d-limonene, ethyl octanoate, ethyl levulinate, benzyl acetate, linalool, vanillin, butyric acid, ethyl decanoate)

- MAL number:

Manufacturer

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Product Registration Holder

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