

BILAXTEN[®] 2.5MG/ML ORAL SOLUTION

Bilastine (10mg)

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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 2 years of age with a body weight below 15 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 pectoris – pain or tightness in the chest area)
- 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 HIV)
- Rifampicin (an antibiotic)

How to use Bilaxten

- How much to use

Bilaxten 2.5mg/ml oral solution is indicated in children aged 2 to 11 years with a body weight of at least 15 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 2 to 11 years of age with a body weight of at least 15 kg is 10 mg bilastine (4 ml of oral solution) once daily for the relief of symptoms of allergic rhinoconjunctivitis and urticaria.

The oral solution is for oral use

- The bottle of oral solution is provided with a child-proof cap and must be opened as follows: press the plastic screw-cap downwards and turn anti-clockwise at the same time
- The oral solution is accompanied by a cup for dosage with a mark of 4 ml (= 10 mg bilastine per

dosing), which will help you to dose the oral solution correctly

- Fill the cup with 4 ml of oral solution
- Administer directly from the cup
- Wash the cup after use

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 oral solution to your child one hour before or two hours after your child has taken any 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.

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- 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 2 years of age with a body weight below 15 kg since no sufficient data are available.

- Things to be careful of

Bilaxten with food, drink and alcohol

The oral solution 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 oral solution 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 solution.

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 2 to 11 years of age with a body weight of at least 15 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.

Bilaxten contains ethanol and sodium

The amount of ethanol in this medicine is small and will not have any noticeable effects.

Bilaxten contains **methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216)** which may cause allergic reactions (possibly delayed).

Side effects

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

If your child experiences symptoms of an allergic reaction the signs of which may include difficulty in breathing, dizziness, collapsing or losing consciousness, swelling of the face, lips, tongue or throat, and/or swelling and redness of the skin, stop giving the medicine and seek urgent medical advice straight away.

Side effects that may be experienced in children are:

Common: may affect up to 1 in 10 people

- allergic conjunctivitis (eye irritation)
- headache

Uncommon: may affect up to 1 in 100 people

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

- nausea (the feeling of being sick)
- eczema
- stomach pain (abdominal / upper abdominal pain)

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
- tiredness
- increased appetite
- irregular heartbeat
- increased weight
- nausea (the feeling of being sick)
- anxiety
- dry or uncomfortable nose
- belly pain/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)

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- Vomiting

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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

The shelf life after first opening is 6 months.

Do not use this medicine if you notice any visible signs of particles.

Do not use this medicine after the expiry date which is stated on the carton and the bottle after EXP. The expiry date refers to the last day of that month

- 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.

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Product Description

- What it looks like

Bilaxten oral solution is a clear, colourless, slightly viscous aqueous solution of pH 3.0-4.0, without precipitate.

Bilaxten 2.5 mg/ml oral solution is packaged in an amber glass bottle, sealed with a polypropylene child-resistant cap, including a 25 ml polypropylene cup for dosage with a mark of 4 ml. Each bottle contains 120 ml of oral solution.

- Ingredients

- Active ingredient(s)

Bilastine. One milliliter of the oral solution contains 2.5 mg of bilastine

- Inactive ingredients

Betadex,(E459), Hydroxyethylcellulose, Methyl parahydroxybenzoate (E218), Propyl parahydroxybenzoate (E216), Sucralose (E955), Raspberry flavour (major components: ethanol, triacetin, water, ethyl butyrate, linalyl acetate), Hydrochloric acid 37% or 10% (for pH-adjustment), Sodium hydroxide (for pH-adjustment), Water, purified.

- MAL number:

MAL21046008ARZ

Manufacturer

Berlin-Chemie AG,
Glienicke Weg 125,
12489 Berlin
Germany.

Product Registration Holder

A. Menarini Singapore Pte. Ltd.
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