

BILAXTEN 20mg Orodispersible Tablets

Bilastine 20mg

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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 or rashes (hives or urticaria).

How Bilaxten works

Bilaxten contains the active substance bilastine which is an antihistamine.

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 you are allergic to bilastine or any of the other ingredients of this medicine (listed in section *Ingredients*).

- Before you start to use it

Do not give this medicine to children under 12 years of age.

Do not exceed the recommended dose. If symptoms persist, consult your doctor.

Talk to your doctor or pharmacist before using Bilaxten if you have moderate or severe renal impairment and in addition you are taking other medicines (see "Other medicines and Bilaxten")

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, please discuss with your doctor if you are taking any of the following medicines:

- 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 AIDS)
- Rifampicin (an antibiotic)

How to use Bilaxten

- How much to use

The recommended dose in adults, including elderly and adolescents aged 12 years and over, is 1 orodispersible tablet (20 mg bilastine) once daily.

- When to use it

You should take the orodispersible tablet one hour before or two hours after intake of any food or fruit juice (see section *Things to be careful of*, "Bilaxten with food, drink and alcohol").

- How long to use it

Regarding the duration of treatment, your physician will determine the type of disease you are suffering from and will determine for how long you should take Bilaxten.

- If you forget to use it

Do not take a double dose to make up for a forgotten dose.

If you forget to take your dose on time, take it as soon as possible,

and then go back to your regular dosing schedule.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you use too much (overdose)

If you, or anyone else, have taken too many Bilaxten orodispersible tablets, contact your doctor or pharmacist immediately or go to the emergency department of your nearest hospital. Please remember to take this medicine pack or this leaflet with you.

If you stop using Bilaxten

Generally, there will be no after-effects when treatment with Bilaxten is stopped.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

While you are using Bilaxten

- Things you must do

Always take this medicine exactly as described in this leaflet or your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

- Things you must not do

Do not let anyone else use your medication.

- Things to be careful of

Bilaxten with food, drink and alcohol

These orodispersible tablets 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:

- take the orodispersible tablet and wait for one hour before taking food or fruit juice or
- if you have taken food or fruit juice, wait for two hours before taking the orodispersible tablet.

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

Pregnancy, breast-feeding and fertility

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.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your 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 you, before driving or operating machinery

Bilaxten contains sodium and ethanol

This medicine contains less than 1 mmol sodium (23 mg) per orodispersible tablet, that is to say essentially 'sodium-free'.

This medicine contains 0.0030 mg of alcohol (ethanol) in each orodispersible tablet which is equivalent to 1,6 mg/100g (0.0016 % w/w). The amount in one orodispersible tablet weighting 185 mg is equivalent to less than 1 ml beer or 1 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

Side effects

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

Stop taking the medicine and seek urgent medical advice straight away, in case you experience symptoms of an allergic reaction 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.

Other 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)
- vomiting

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. 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 Bilaxten

- Storage

Store below 30°C and protect from moisture.

- 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 20mg orodispersible tablets are round, flat, white, engraved with "20" on one side and of 8 mm diameter.

OPA/Alu/PVC/Alu perforated unit-dose blisters of 4 x 1, 10 x 1, 20 x 1, 30 x 1, 40 x 1, 50 x 1 orodispersible tablets packaged in cardboard boxes.

Not all pack sizes may be marketed.

BILAXTEN 20mg Orodispersible Tablets

Bilastine 20mg

- Ingredients

- Active ingredient(s)

Bilastine. Each orodispersible tablet contains 20 mg of bilastine.

- Inactive ingredients

Mannitol (E421), croscarmellose sodium, sodium stearyl fumarate, sucralose (E955), red grape flavour (major components: gum arabic, ethyl butyrate, triacetin, methyl anthranilate, ethanol, d-limonene, linalool)

- MAL number

MALXXXXXXXXX

Manufacturer

FAES FARMA S.A.

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Product Registration holder

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