PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Bilastine Teva 20 mg orodispersible tablets
bilastine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What [PRODUCT NAME] is and what it is used for
2. What you need to know before you take [PRODUCT NAME]
3. How to take [PRODUCT NAME]
4. Possible side effects
5. How to store [PRODUCT NAME]
6. Contents of the pack and other information

1. What [PRODUCT NAME] is and what it is used for

Bilastin Teva contains the active substance bilastine which is an antihistamine.

Bilastin Teva 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).

Bilastin Teva 20 mg tablets are indicated in in adults and adolescents.

2. What you need to know before you take [PRODUCT NAME]

Do not use [PRODUCT NAME]
- if you are allergic to bilastine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using [PRODUCT NAME] if you have moderate or severe renal impairment, low blood levels of potassium, magnesium, calcium, if you have or had heart rhythm problems or if your heart rate is very low, if you are taking medicines that may affect the heart rhythm, if you have or had a certain abnormal pattern to your heart beat (known as prolongation of the QTc interval on the Electrocardiogram) which can occur in some forms of heart disease and in addition you are taking other medicines (see “Other medicines and [PRODUCT NAME]”).

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

Other medicines and [PRODUCT NAME]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- Ketoconazole tablets (used to treat Cushing's syndrome, when the body produces an excess of cortisol.)
- Erythromycin (an antibiotic)
- Diltiazem (to treat pain or tightness in the chest area- angina pectoris)
- 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)

[PRODUCT NAME] with food, drink and alcohol
These 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 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 tablet.

Bilastine, at the dose recommended for adults (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.

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

3. How to take [PRODUCT NAME]

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

The recommended dose in adults, including elderly and adolescents aged 12 years and over, is 20 mg once daily.

Use in children
Other pharmaceutical forms of this medicine – bilastine 10 mg orodispersible tablets or bilastine 2.5 mg/mL oral solution - may be more suitable for children 6 to 11 years of age with a body weight of at least 20 kg.

Ask your doctor or pharmacist.

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.

- The tablet is for oral use.
- Place the tablet in your mouth. It will disperse rapidly in saliva and can then be easily swallowed.
- Alternatively, you may disperse the tablet in a teaspoon of water before taking it. It has to be ensured that none of the medicine remains in the spoon.
- You should use exclusively water for dispersion, do not use grapefruit juice or any other fruit juices.
- The tablet must be taken one hour before or two hours after intake of food or fruit juice. See section 2, "[PRODUCT NAME] with food, drink and alcohol".

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 [PRODUCT NAME].

If you take more [PRODUCT NAME] than you should

If you, or anyone else, have taken too many [PRODUCT NAME], 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 forget to take [PRODUCT NAME]
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 stop taking [PRODUCT NAME]
Generally, there will be no after-effects when treatment with [PRODUCT NAME] is stopped.

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

4. Possible side effects

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

If 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, stop taking the medicine and seek urgent medical advice straight away.

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 heartbeat)
- tachycardia (fast heartbeat)
- vomiting

Side effects that may be experienced in children are:

Common: *may affect up to 1 in 10 people*
- rhinitis (nasal irritation)
- allergic conjunctivitis (eye irritation)
- 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

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [PRODUCT NAME]

Keep this medicine out of the sight and reach of children.

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

This medicine does not require any special storage conditions.

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 to protect the environment.

6. Contents of the pack and other information

What [PRODUCT NAME] contains

- The active substance is bilastine.
  Each tablet contains 20 mg of bilastine.

- The other ingredients are:
  Mannitol (E 421), cellulose microcrystalline, croscarmellose sodium (see section 2 "[PRODUCT NAME] contains sodium"), magnesium aluminometasilicate, sucralose, strawberry flavour, magnesium stearate, silica colloidal anhydrous

What [PRODUCT NAME] looks like and contents of the pack

[PRODUCT NAME] 20 mg orodispersible tablets are approximately 10.3 x 5.5 mm, white to off-white, plain to mottled, biconvex, oval shaped tablets, debossed with '20' on one side and plain on the other side.

The tablets are supplied in blisters of 10, 20, 30 or 50 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

[To be completed nationally]

{Name of the Member State}: {Name of the medicinal product}
{Name of the Member State}: {Name of the medicinal product}

This leaflet was last revised in 2025-02-25