PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Bilaxten

Tablets

Active ingredient:
Each Bilaxten tablet contains: bilastine 20 mg.
For the list of the additional ingredients see section 6.
See also "Important information about some of the medicine's ingredients" in section 2.
Read the entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for treatment of your condition. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

The medicine is intended for treatment of symptoms of allergic rhinitis and allergic conjunctivitis (seasonal or perennial) and itchy skin rashes (urticaria/hives) in adults and adolescents over the age of 12.
Therapeutic class: anti-histamines.

2. Before using the medicine

Do not use the medicine if:

You are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (for the list of additional ingredients, see section 6).

Special warnings regarding the use of the medicine:
If symptoms persist, consult the doctor. Do not exceed the recommended dose.

Before starting treatment with Bilaxten, tell your doctor:
If you suffer or have suffered in the past from moderate to severe renal impairment, from low levels of potassium, magnesium, calcium in the blood, if you have or have 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 have had a certain abnormal heart rate pattern (known as QTC interval prolongation in electrocardiogram) which may occur in certain forms of heart diseases and if you are taking other medicines (see "Drug interactions").

Children and adolescents:
The medicine should not be used in children under the age of 12.

Drug interactions:
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. In particular, you should inform the doctor or pharmacist if you are taking the following medicines (note that the following list mentions the active ingredients in the medicines. If you are not sure whether you are using any of these medicines, please consult the doctor or pharmacist):
- Ketoconazole (for treatment of fungal infection), ritonavir (against HIV).
- Erythromycin or rifampicin (antibiotics).
- Cyclosporine (an immunosuppressant medicine).
- Diltiazem (for treatment of angina pectoris).

Use of the medicine and food:
The medicine should not be taken with food or with grapefruit juice or other fruit juices, as this may decrease the effect of the medicine. In order to avoid this, you can:
- Take the medicine one hour before eating or drinking fruit juice.
- Take the medicine two hours after eating or drinking fruit juice.

Use of the medicine and alcohol consumption:
At the recommended dosage, the medicine does not increase the drowsiness caused by drinking alcohol.

Pregnancy, breastfeeding and fertility:
Consult a doctor if you are pregnant, think you are pregnant, are planning a pregnancy or breastfeeding.
There is no information regarding the use of Bilaxten in pregnant or breastfeeding women.
There is no information regarding the effect of Bilaxten on fertility.

Driving and use of machinery:
Bilaxten is not likely to affect your ability to drive or operate machinery. However, each patient may react differently to the medicine. Therefore, you should check how the medicine affects you before you drive or operate machinery.

Important information about some of the medicine's ingredients
Each tablet of Bilaxten contains less than 23 mg sodium and can therefore be considered nearly sodium-free.

3. How to use the medicine?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and how to use the medicine.
The dosage and treatment regimen will be determined only by the doctor.

The usual dose is:
Take one tablet a day with a glass of water.
The tablet is intended for oral administration (by mouth).
Take the tablet one hour before or two hours after eating or drinking fruit juice. See also "Use of the medicine and food".
The duration of treatment will be determined by the doctor.
Do not exceed the recommended dose.
The score line is not intended for dividing the tablet into halves that contain equal doses, but to help you break the tablet in order to make it easier to swallow. Both parts should be swallowed immediately after halving.
There is no information regarding crushing or chewing the tablet.
If you accidentally took a higher dosage:
If you took an overdose or if a child or any person accidentally swallowed this medicine, immediately refer to a doctor or to a hospital emergency room and bring the medicine's package with you.
If you forgot to take the medicine at the specified time, take a dose as soon as you remember and then resume the regular schedule. Do not take a double dose in order to compensate for the forgotten dose.
Adhere to the treatment as recommended by the doctor. Even if there is an improvement in your state of health, do not stop treatment with the medicine without consulting the doctor.
Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Bilaxten may cause side effects in some users. If the side effects persist, are bothersome or if they worsen, consult the doctor. Do not be alarmed when reading the list of side effects, you may not experience any of them.
Stop taking the medicine and seek immediate medical assistance if the following serious side effects occur:
Allergic reactions. The symptoms may include rash, breathing difficulties, dizziness, collapsing or losing consciousness; swelling of the face, lips, tongue or throat and/or swelling and redness of the skin.

Additional side effects:
Common side effects (occur in 1-10 users out of 100):
Headache, drowsiness.
Uncommon side effects (occur in 1-10 users out of 1,000):
Abnormal ECG (heart test) results; changes in liver function or renal function blood tests; dizziness; abdominal pain or discomfort (including in the upper abdomen); tiredness, increased appetite, irregular heartbeat, increased weight, nausea, anxiety, dry or uncomfortable nose, diarrhea, inflammation of the stomach (gastritis), vertigo (feeling of dizziness or spinning), weakness, thirst, breathing difficulties, dry mouth, indigestion, itching, cold sores (oral herpes), fever, ringing in the ears (tinnitus), difficulty in sleeping, increased blood fats.
Side effects with unknown frequency (effects whose frequency has not yet been determined):
Palpitations (feeling your heartbeats), tachycardia (a fast heartbeat), vomiting.
If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.
Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which leads to the online form for reporting side effects, or by clicking on the link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: store below 30°C.

6. Additional information

In addition to the active ingredient, the medicine also contains the following inactive ingredients:
Cellulose, microcrystalline; Sodium starch glycolate; Silica, colloidal anhydrous; Magnesium stearate (vegetable).

What does the medicine look like and what does the package contain?
White, oval, convex tablets with a score line. The tablets are packed in a blister pack. Each package contains 2, 10 or 30 tablets.
Not all package sizes may be marketed.
Registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.
Manufacturer: Faes Farma S.A, Spain.
Medicine registration number in the national medicines registry of the Ministry of Health: 1590634829
Revised in May 2025.

194964 964004-F