Patient Leaflet According to the Pharmacists' Regulations (Preparations) - 1986

This medicine is sold with a doctor's prescription only

Bilaxten

Tablets

Active ingredient:
Each tablet of Bilaxten contains: 20 mg bilastine
For a list of the other ingredients, please see section 6.

Read the entire leaflet carefully before using this medicine.
This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.
This medicine has been prescribed for the 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 to yours.

1. What is the medicine intended for?

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

2. Before using this medicine

Do not use this medicine if:

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

Special warnings regarding the use of this medicine:
If the symptoms continue, consult your 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 kidney function impairment.

Use in children:
Do not use this medicine in children under the age of 12.

Drug interactions: If you are taking or have recently taken any other medicines, including non-prescription medicines and nutrition supplements, please tell your doctor or pharmacist.
Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list mentions the active ingredients of the medicines. If you are unsure whether you are using any of these medicines, please consult with your doctor or pharmacist):

- Ketoconazole (for the treatment of fungal infection), ritonavir (against the HIV virus).

- Erythromycin or rifampicin (antibiotics).
- Ciclosporin (a medicine which supresses the immune system).
- Diltiazem (for the treatment of angina pectoris).

Use of the medicine with food and beverages:
Do not take the medicine with food, or with grapefruit juice or other fruit juices, since this may reduce the effect of the medicine. In order to avoid this, you may:

- Take the medicine one hour before eating food or drinking fruit juice.
- Take the medicine two hours after eating food or drinking fruit juice.

Use of this medicine and alcohol consumption:
The medicine, at the recommended dosage, does not increase drowsiness resulting from alcohol drinking.

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

Driving and use of machinery:
Bilaxten is unlikely to affect your ability to drive or operate machinery. However, each patient may respond differently to the medicine. Therefore, you should check how the medicine affects you, before you drive or operate machinery.

3. How to use this medicine?
Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure regarding the dosage and the manner of treatment with the medicine.
The dosage and the manner of treatment will be determined by the doctor only.

The standard dosage is usually:
Take one tablet a day with a glass of water. The tablet is intended to be taken orally (by mouth).
Take the tablet one hour before or two hours after eating food or drinking fruit juices. See also 'Use of the medicine with food and beverages'.
The duration of treatment will be determined by your doctor.
Do not exceed the recommended dose.
The score line is not intended for dividing the tablet into halves containing equal doses, rather, it can assist in dividing the tablet for easier swallowing. Both parts should be swallowed immediately after halving.
There is no information regarding crushing or chewing of the tablet.

If you have accidentally taken a higher dosage: If you have taken an overdose, or if a child or any person has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.
If you forgot to take this medicine at the set time, take a dose as soon as you remember and then go back to your regular dosing schedule. Do not take a double dose to make up for the forgotten dose.
Continue the treatment as recommended by your doctor. Even if your state of health improves, do not stop treatment with the medicine without consulting with your 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 any further questions regarding the use of this medicine, consult your doctor or pharmacist.

4. Side effects:

Like any medicine, the use of Bilaxten may cause side effects in some users.
If the side effects persist or they are bothersome or worsen, consult your doctor.
Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Stop taking the medicine and seek urgent 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 (appear in 1-10 users out of 100):
Headache, drowsiness.

Uncommon side effects (appear in 1-10 users out of 1,000):
Abnormal ECG (heart test) results; changes in blood tests for liver functions or renal functions; dizziness; abdominal pain or discomfort (including the upper abdomen); tiredness, increased appetite, irregular heartbeat, weight gain, nausea, anxiety, discomfort or dryness in the nose, diarrhea, inflammation of the stomach (gastritis), vertigo (feeling of dizziness or spinning), weakness, thirst, difficulty breathing, dry mouth, indigestion, itchiness, cold sores (oral herpes), fever, ringing in the ears (tinnitus), sleeping difficulties, increase in blood fats.

Side effects of unknown frequency (effects whose frequency has not yet been determined):
Palpitations (feeling your heart beat), tachycardia (rapid heartbeat), vomiting.

If a side effect appears, if one of the side effects worsens or when you suffer from a side effect not mentioned in this leaflet, consult with your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a 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 (type A); Silica, colloidal anhydrous; Magnesium stearate.

What does the medicine look like and what does the package contain?
White, oval, convex tablets with score line. The tablets are packaged in blister packs of 2, 10 or 30 tablets in each package.
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 Drug Registry of the Ministry of Health:1590634829
This leaflet was checked and approved by the Ministry of Health in August 2017, and updated according to the guidelines of the Ministry of Health in December 2019.

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