

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'  
REGULATIONS (PREPARATIONS) – 1986**

This medicine is dispensed with a doctor's prescription only

**Bilaxten®**

**Tablets**

**Active ingredient:**

Each tablet of Bilaxten contains: 20 mg bilastine.

For the list of the additional ingredients, please see section 6.

See also 'Important information about some of the medicine's ingredients' in section 2.

**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 the 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 conjunctivitis (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 the medicine**

**Do not use the medicine if:**

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

**Special warnings regarding the use of the medicine:**

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

**Before starting treatment with Bilaxten tell the doctor:**

If you suffer or have suffered in the past from moderate to severe kidney function impairment.

**Children and adolescents:**

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 nutritional supplements, tell the doctor or pharmacist.**

Especially inform the 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 the doctor or pharmacist):

- Ketoconazole (for the treatment of fungal infection), ritonavir (against the HIV virus).
- Erythromycin or rifampicin (antibiotics).
- Ciclosporin (a medicine which suppresses the immune system).
- Diltiazem (for the treatment of angina pectoris).

**Use of the medicine and food:**

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 the medicine and alcohol consumption:**

The medicine, at the recommended dosage, does not increase drowsiness resulting from alcohol drinking.

**Pregnancy, breastfeeding and fertility:**

Consult the doctor if you are pregnant, think you are pregnant, are 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, check how the medicine affects you, before you drive or operate machinery.

**Important information about some of the medicine's ingredients**

Each Bilaxten tablet contains less than 23 mg sodium, therefore can be considered as almost 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 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 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 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 medicine package with you.

**If you forgot to take the 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.

Adhere to the treatment as recommended by the doctor. Even if your state of health improves, do not stop treatment with the medicine without consulting with 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 any further questions regarding the use of the medicine, consult the doctor or pharmacist.**

#### **4. Side effects**

As with any medicine, the use of Bilaxten may cause side effects in some users. If the side effects persist or they are bothersome or they worsen, consult the 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 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 (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, breathing difficulties, 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 the leaflet, consult with the 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](http://www.health.gov.il)) which leads 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 babies, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by 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 packaged in blister packs. 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 Drug Registry of the Ministry of Health:**1590634829

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