

## PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

### ILAXTEN 20 MG 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 ILAXTEN is and what it is used for
2. What you need to know before you take ILAXTEN
3. How to take ILAXTEN
4. Possible side effects
5. How to store ILAXTEN
6. Contents of the pack and other information

#### **1. What Ilaxten is and what it is used for**

ILAXTEN contains the active substance bilastine which is an antihistamine. ILAXTEN 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).

#### **2. What you need to know before you take Ilaxten 20 mg tablets**

##### **Do not take Ilaxten**

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 Ilaxten if you have moderate or severe renal impairment and in addition you are taking other medicines (see “Other medicines and Ilaxten”).

##### **Children**

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

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

### **Other medicines and Ilaxten**

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)
- 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 HIV)
- Rifampicin (an antibiotic)

### **ILAXTEN 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 recommended dose (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.

### **Ilaxten 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 Ilaxten**

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

The recommended dose in **adults**, including the elderly and adolescents aged 12 years and over, is 1 tablet (20 mg) a day.

- The tablet is for oral use.
- The tablet must be taken one hour before or two hours after intake of food or fruit juice (see section 2, Ilaxten with food, drink and alcohol”).
- Swallow your tablet with a glass of water.
- The score line is only here to help you break the tablet if you have difficulty swallowing it whole

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 ILAXTEN.

### **Use in children**

Other forms of this medicine - orodispersible tablets or 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 bilastine to children under 6 years of age with a body weight below 20 kg since no sufficient data are available.**

### **If you take more ILAXTEN than you should**

If you, or anyone else, have taken too many ILAXTEN 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 forget to take ILAXTEN**

**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.

## **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.

**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

**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 Yellow Card Scheme. Website: <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Ilaxten**

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 ILAXTEN contains**

- The active substance is bilastine. Each tablet contains 20 mg of bilastine.
- The other ingredients are cellulose microcrystalline, sodium starch glycolate type A (derived from potato), colloidal anhydrous silica, magnesium stearate.

**What ILAXTEN looks like and contents of the pack**

ILAXTEN tablets are white, oval, biconvex and scored (length 10 mm, width 5 mm).

The tablets are supplied in blisters of 10, 20 , 30, 40 or 50 tablets

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Menarini International Operations Luxembourg S.A.

1 Avenue de La Gare

L-1611 Luxembourg

**Manufacturer**

A.Menarini Manufacturing Logistics and Services S.r.l.

Campo di Pile

L'Aquila

Italy

***Marketed by:***

A. Menarini Farmaceutica Internazionale SRL.

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria: Olisir 20 mg Tabletten

Belgium: Bellozal 20 mg Tablet

Bulgaria: Fortecal 20 mg Таблетка

Cyprus: Bilaz 20 mg Δισκίο

Czech Republic: Xados

Denmark: Revitelle, tabletter 20 mg

Estonia: Opexa

Finland: Revitelle 20 mg Tabletti

France: Bilaska 20 mg Comprimé

Germany: Bilaxten 20 mg Tabletten

Greece: Bilaz 20 mg Δισκίο

Hungary: Lendin 20 mg tableta

Iceland: Bilaxten 20 mg töflur

Ireland: Drynol 20 mg tablets

Italy: Bysabel 20 mg Compressa

Latvia: Opexa 20 mg tabletes

Lithuania: Opexa 20 mg Tabletis

Luxembourg: Bellozal 20 mg Tablet

Malta: Gosall 20 mg tablets

Norway: Zilas 20 mg tablett

Poland: Clatra

Portugal: Lergonix 20 mg Comprimido

Romania: Borenar 20 mg comprimate

Slovak Republic: Omarit

Slovenia: Bilador 20 mg tablete

Spain: Ibis 20 mg comprimidos

Sweden: Bilaxten 20 mg Tablett

United Kingdom (Northern Ireland): Ilaxten 20 mg tablets

**This leaflet was last revised in 03/2023.**