

## **Package leaflet: Information for the patient**

### **Ilaxten 10 mg orodispersible tablets**

**For children aged 6 to 11 years with a body weight of at least 20 kg**

bilastine

**Read all of this leaflet carefully before your child starts 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 your child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets 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).

Ilaxten 10 mg orodispersible tablets are indicated in children aged 6 to 11 years with a body weight of at least 20 kg.

#### **2. What you need to know before you use Ilaxten**

##### **Do not use Ilaxten:**

- if your child is 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 your child has moderate or severe renal or hepatic impairment or if your child is taking other medicines (see "Other medicines and Ilaxten").

##### **Children**

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.

##### **Other medicines and Ilaxten**

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines, including medicines obtained without a prescription. Some medicines should not be taken together and others may need their doses to be altered when taken together.

Always inform your doctor or pharmacist if your child is using or receiving any of the following medicines in addition to Ilaxten:

- Ketoconazole (an antifungal medicine)
- Erythromycin (an antibiotic)
- Diltiazem (to treat angina pectoris – pain or tightness in the chest area)
- 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)

### **Ilaxten with food, drink and alcohol**

These orodispersible tablet 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:

- give your child the orodispersible tablet and wait for one hour before your child takes food or fruit juice or
- if your child has taken food or fruit juice, wait for two hours before giving him the orodispersible tablet.

Bilastine, at the dose recommended in adults (20 mg), does not increase the drowsiness produced by alcohol.

### **Pregnancy, breast-feeding and fertility**

This medicine is for use in children from 6 to 11 years of age with a body weight of at least 20 kg. However, the following information should be noted regarding the safe use of this medicine. 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.

In case of pregnancy or breast-feeding, or when planning to have a baby, it is recommended to ask to the 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 your child, before you let your child ride bicycles or drive other vehicles or operate machinery.

### **Ilaxten contains ethanol and sodium**

This medicine contains 0.0015 mg of alcohol (ethanol) in each orodispersible tablet which is equivalent to 1 mg/100 g (0.001% w/w). The amount in one orodispersible tablet is equivalent to less than 0.00004 ml beer or 0.00002 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains less than 1 mmol sodium (23 mg) per orodispersible tablet, that is to say essentially 'sodium free'.

## **3. How to take Ilaxten**

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

### **Use in children**

The recommended dose in children 6 to 11 years of age with a body weight of at least 20 kg is 10 mg bilastine (1 orodispersible tablet) once daily for the relief of symptoms of allergic rhinoconjunctivitis and urticaria.

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.

For adults, including elderly and adolescents aged 12 years and over, the recommended dose is 20 mg bilastine once daily. For this patient population a more suitable dosage form – tablet - is available, ask your doctor or pharmacist.

- The orodispersible tablet is for oral use.
- Please place the orodispersible tablet in the mouth of your child. It will disperse rapidly in saliva and can then be easily swallowed.
- Alternatively, you may disperse the orodispersible tablet in a tea-spoon of water before giving it to your child. It has to be ensured that no rest of sediment remains in the spoon.
- **You should use exclusively water for dispersion**, do not use grapefruit juice or any other fruit juices.
- You should give the orodispersible tablet to your child one hour before or two hours after your child has taken any food or fruit juice.

As the duration of treatment depends on your child's underlying disease, your physician will determine for how long your child should take Ilaxten.

### **If you use more Ilaxten than you should**

If your child, or anyone else, use too much of this medicine, tell your doctor 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 use Ilaxten**

If you forget to give your child the daily dose on time, give it on the same day as soon as you remember. Then, give the next dose on the next day at the usual time as prescribed by the doctor. In any case, do not give a double dose to make up for a forgotten one.

### **If you stop using Ilaxten**

Generally, there will be no after-effects when treatment with Ilaxten 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 your child experiences symptoms of an allergic reaction the signs of which may include difficulty in breathing, dizziness, collapsing or losing consciousness, swelling of the face, lips, tongue or throat, and/or swelling and redness of the skin, stop giving the medicine and seek urgent medical advice straight away.

### **Other 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

**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

### **Reporting of side effects**

If your child gets 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 at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) 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 blister 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 protect the environment.

## **6. Contents of the pack and other information**

### **What Ilaxten contains**

- The active substance is bilastine. Each orodispersible tablet contains 10 mg of bilastine.
- The other ingredients are mannitol (E421), croscarmellose sodium, sodium stearyl fumarate, sucralose (E955), red grape flavour (major components: gum arabic, ethyl butyrate, triacetin, methyl anthranilate, ethanol, d-limonene, linalool)

### **What Ilaxten looks like and contents of the pack**

Ilaxten orodispersible tablets are round, slightly biconvex, white, of 8 mm diameter.

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

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

*Marketing Authorisation Holder*

Menarini International Operations Luxembourg S.A.

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