

## Package Leaflet: Information for the user



# Hayfever Relief Instant-Melts 10 mg Orodispersible Tablets (Loratadine)

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 10 days.

### **What is in this leaflet:**

1. What Hayfever Relief Instant-Melts 10 mg Orodispersible Tablets (Hayfever Relief Instant-Melts) is and what it is used for
2. What you need to know before you take Hayfever Relief Instant-Melts
3. How to take Hayfever Relief Instant-Melts
4. Possible side effects
5. How to store Hayfever Relief Instant-Melts
6. Contents of the pack and other information

### **1. WHAT HAYFEVER RELIEF INSTANT-MELTS IS AND WHAT IT IS USED FOR**

Hayfever Relief Instant-Melts belong to a class of medicines known as antihistamines.

Antihistamines help to reduce allergic symptoms by preventing the effects of a substance called histamine, which is produced in the body.

The tablet relieves symptoms associated with allergic rhinitis (for example, hayfever) such as sneezing, runny or itchy nose and burning or itchy eyes.

The tablet may also be used to help relieve symptoms of urticaria (itching and redness), which is often known as hives or nettle rash.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE HAYFEVER RELIEF INSTANT-MELTS**

#### **Do not take Hayfever Relief Instant-Melts:**

- if you are allergic to loratadine, or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant or breastfeeding
- if you have phenylketonuria (a metabolism disorder)

**Warnings and precautions:**

Talk to your doctor or pharmacist before taking Hayfever Relief Instant-Melts:

- if you have severe liver disease
- if you have to undergo any skin tests, it may be necessary to stop taking this medicine at least 2 days before the test to make sure the result of the test is correct.

**Children**

Hayfever Relief Instant-Melts is not recommended for children younger than 2 years old as efficacy and safety have not been established. Do not give Hayfever Relief Instant-Melts to children between 2 and 12 years old who weigh less than 30 kg. There are other more suitable formulations.

**Other medicines and Hayfever Relief Instant-Melts**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Potential interaction may occur with medicines that make some liver enzymes less active resulting in elevated levels of loratadine. This may cause an increase in adverse events.

**Hayfever Relief Instant-Melts with food, drink and alcohol**

The tablets can be taken with or without a meal.

The tablets will normally disintegrate in the mouth in contact with saliva, therefore water or other liquids are not normally needed.

Loratadine has not been shown to add to the effects of an alcoholic drink.

**Pregnancy, breast-feeding and fertility**

The use of Loratadine during pregnancy and breast-feeding is **not recommended**. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are nursing a baby, taking Hayfever Relief Instant-Melts is not recommended, because loratadine is excreted in breast milk.

**Driving and using machines**

In clinical studies that assessed driving ability, no impairment was observed in patients receiving loratadine.

At the recommended dose, Hayfever Relief Instant-Melts are not expected to cause you to be drowsy or less alert. However, very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

**Hayfever Relief Instant-Melts contain lactose.**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor or pharmacist before taking this medicine.

**Hayfever Relief Instant-Melts** contains less than 7 mg **sorbitol** in each orodispersible tablet.

Hayfever Relief Instant-Melts contains less than 1 mmol sodium (23 mg) per orodispersible tablet, that is to say essentially 'sodium-free'.

**Hayfever Relief Instant-Melts contain 0.5 mg aspartame in each orodispersible tablet.**

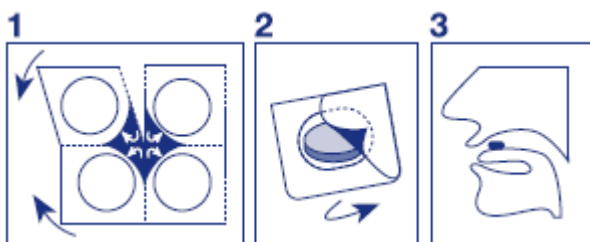
Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

**3. HOW TO TAKE HAYFEVER RELIEF INSTANT-MELTS**

Always take Hayfever Relief Instant-Melts exactly as described in this leaflet or your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Hayfever Relief Instant-Melts is intended to be put on the tongue (see below) and for oral use.

Hayfever Relief Instant-Melts break easily, so you should handle the tablets carefully and with dry hands only.



**Method of use**

1. Tear one blister unit along the perforations.
2. Peel open the backing in direction of the arrow and take the tablet out carefully. The tablet should not be pushed through the backing.
3. Put the tablet on your tongue as soon as it is removed from the packaging. It will melt in your mouth directly. Water is not required to swallow the tablet.

Hayfever Relief Instant-Melts are dispersed in your mouth in contact with saliva and can be therefore taken without water. They have a sweet orange taste.

**Giving this medicine to children**

It is important to know how much your child weighs to make sure that you give the correct amount of medicine. For example, a 9 year old child weighs about 30kg (four and half stone).

If in doubt weigh your child and then follow the instructions in the table.

Do not give to children under 2 years or who weigh less than 30kg (four and half stone).

The recommended dose is:

<b>Age</b>	<b>How many to take</b>	<b>How often to take</b>
Adults and children over 12 years	One tablet	Once a day
Children of 2 to 12 years who weigh <b>more than</b> 30kg (four and half stone)	One tablet	Once a day
Children of 2 to 12 years who weigh <b>less than</b> 30kg (four and half stone)	<b>Do not give</b> this medicine.	
If you have severe liver problems your doctor or pharmacist may advise you to take the recommended amount every other day. If this applies to you follow their instructions.		

**Duration of treatment:**

You must contact a doctor if your symptoms do not improve or even get worse after 10 days.

**If you take more tablets than you should:**

If you take more Hayfever Relief Instant-Melts than recommended, contact your doctor or pharmacist. Taking more tablets than recommended may cause drowsiness, rapid heart beat and headache.

**If you forget to take Hayfever Relief Instant-Melts:**

If you forget to take your dose on time, take it as soon as possible, then go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten tablet.

**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.

**The most commonly reported side effects in adults and children over 12 years of age are:**

- drowsiness
- headache
- increased appetite
- difficulty sleeping

**The most commonly reported side effects in children aged 2 to 12 years are:**

- headache
- nervousness
- tiredness

**Very rare side effects (may affect up to 1 in 10,000 people) have also been observed during the marketing of loratadine:**

- severe allergic reactions (including swelling)
- dizziness
- convulsion
- fast or irregular heartbeat
- nausea (feeling sick)
- dry mouth
- upset stomach
- liver problems
- hair loss
- rash
- tiredness

**Not known**, frequency cannot be estimated from the available data:

- weight increased

#### **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 [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 HAYFEVER RELIEF INSTANT-MELTS**

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 blister after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

Do not throw away 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 Hayfever Relief Instant-Melts contains**

- The active substance is loratadine.
- Each orodispersible tablet contains 10 mg loratadine.
- The other ingredients are sweet orange flavour, aspartame (E951), citric acid anhydrous (E330), silica colloidal anhydrous (E551), maize starch dried, lactose anhydrous, magnesium stearate (E470b), croscarmellose sodium (E468), mannitol (E421), sorbitol (E420), crospovidone, silica colloidal hydrated (E551), polysorbate 80 (E433), povidone (E1201), microcrystalline cellulose (E460).

**What Hayfever Relief Instant-Melts looks like and contents of the pack**

Hayfever Relief Instant-Melts tablets are white, round and flat.

The packs may contain 7, 14, 21 or 30 orodispersible tablets, packed in aluminium/aluminium unit dose perforated blisters.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Manufactured for The Boots Company PLC, Nottingham, NG2 3AA UK by Lek Pharmaceuticals d.d. Verovškova 57, 1526 Ljubljana, Slovenia.

Marketing Authorisation held by Sandoz Limited, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, UK.

**This leaflet was last revised in February 2019.**

**Other Formats**

To request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only). Please be ready to give the following information:

Product name: Boots Hayfever Relief Instant-Melts 10mg Orodispersible Tablets

Reference number: 04416/0693.

This is a service provided by the Royal national Institute of Blind People.

Artwork reference: WBAG315812J