

Labixten[®] and Labixten[®] Meltlets

Consumer Leaflet

Active ingredient: bilastine

Patient information

Please read this leaflet carefully before you start taking Labixten and Labixten Meltlets (hereafter referred to as Labixten unless otherwise stated) because it contains important information for you.

This leaflet contains some common questions about Labixten. It does not take the place of talking to your healthcare professional.

All medicines have risks and benefits.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine as you may need to read it again.

What is in this leaflet:

1. What is Labixten used for
2. What you need to know before you take Labixten
3. How to take Labixten
4. Possible side effects
5. How to store Labixten
6. Product details

1. What is Labixten used for

Labixten contains the active ingredient bilastine which is a non-drowsy antihistamine. It is fast acting and provides 24 hour hayfever and allergy relief.

Labixten is used to:

- relieve the symptoms of hayfever (sneezing, itchy, runny, blocked nose and red watery and itchy eyes) and other forms of allergic rhinitis
- treat itchy skin rashes (hives or urticaria).

Labixten (bilastine 20 mg tablet) is indicated for adults and adolescents 12 years and over.

Labixten Meltlets (bilastine 10 mg orodispersible tablet) is indicated for children aged 6-11 years with a body weight of at least 20 kg.

2. What you need to know before you take Labixten

Do not take Labixten if you are allergic to bilastine or any of the ingredients listed at the end of this leaflet.

Warnings and precautions

Talk to your healthcare professional before taking Labixten if you have moderate or severe kidney problems and are also taking other medicines listed further below.

Children

Do not give Labixten (bilastine 20 mg) to children under 12 years of age. The safety and how well it works has not been studied in children younger than 12 years of age.

Do not give Labixten Meltlets (bilastine 10 mg) to children under the age of 6 years and/or with a body weight below 20 kg. The safety and how well it works has not been studied in children younger than 6 years of age with a body weight below 20 kg.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription.

In particular, please discuss with your doctor if you are taking any of the following medicines:

- Erythromycin (an antibiotic)
- Diltiazem (to treat angina)
- Ciclosporin (to reduce the activity of your immune system)

Pregnancy, breastfeeding and fertility

There is limited data available on use in pregnant women, during breastfeeding, and on fertility.

Consult your healthcare professional before taking Labixten if you are pregnant or breastfeeding or are planning to have a baby.

Effects on ability to drive or use machinery

It has been demonstrated that bilastine does not affect adult driving performance. However, the response from each patient to the medicine may be different.

Although this medicine is unlikely to affect your ability to ride bicycles, drive other vehicles or operate machinery, a few people may be impaired and care should be taken.

3. How to take Labixten

Adults and adolescents 12 years and over: Take one 20 mg tablet daily with a glass of water for as long as required.

Children 6-11 years, who weight at least 20 kg: Take one 10 mg meltlet for as long as required.

Take Labixten on an empty stomach, either at least one hour before or two hours after having food or fruit juice (such as grapefruit). Food and fruit juice can interfere with the absorption of Labixten by the body.

When to take it

Take Labixten at about the same time each day. Labixten provides fast acting 24 hour symptom relief. Taking it at the same time each day will have the best effect. It may take up to 1 hour for you to experience relief of your allergy symptoms.

How long to take it

Labixten helps control your condition, but it does not cure it. You can stop taking Labixten when you know you are no longer exposed to your hayfever/ allergy triggers, or you know you have obtained sufficient relief from your symptoms.

Labixten can be restarted if your symptoms recur or are expected to recur.

Speak to your healthcare professional if you are unsure how long you should take Labixten for. If symptoms persist, consult your healthcare professional.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Labixten.

Do this even if there are no signs of discomfort or poisoning.

4. Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking Labixten.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Do not be alarmed by the following lists of side effects. You may not experience any of them. Similar side effects were seen in patients taking 'dummy' or placebo tablets during the clinical studies.

Mild side effects that may be experienced in adults and adolescents:

- headache
- drowsiness or tiredness
- dizziness
- mild stomach upsets such as stomach pain, belly pain, nausea or diarrhoea
- indigestion
- increased appetite or weight
- dry or uncomfortable nose
- thirst and dry mouth
- itching
- fever
- cold sores
- irregular heartbeat
- tinnitus (ringing in the ears)
- vertigo (a feeling of dizziness or spinning)

Mild side effects that may be experienced in children:

- headache
- dizziness
- eye redness, itching and watery discharge (allergic conjunctivitis) or eye irritation
- nasal irritation including sneezing, itchy, runny or congestion (rhinitis)
- stomach pain, nausea or diarrhoea
- fatigue

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lip, mouth or throat which may cause difficulty in swallowing or breathing
- swelling and redness of the skin
- collapsing or losing consciousness

These are very serious side effects. If you notice any of them, you may have had a serious allergic reaction to Labixten. You may need urgent medical attention or hospitalisation. These side effects are rare.

Other side effects not listed here may occur in some people.

5. How to store Labixten

Keep this medicine out of sight and reach of children.

Do not take if the blister seal is broken. Do not take this medicine after the expiry date printed on the carton and blister.

Store in a cool, dry place away from sunlight where the temperature stays below 30°C.

6. Product details

Labixten are white, oval, biconvex and scored tablets. The tablets are available in packs of 4, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110 and 120 tablets. Not all pack sizes may be supplied.

Labixten Meltlets are round, slightly biconvex, white orodispersible tablets. The meltlets are available in packs of 4, 10, 20, 30, 50, 60, 70, 80, 90, 100, 110 and 120 meltlets. Not all pack sizes may be supplied.

What Labixten contains

Active ingredient (main ingredient)	Each tablet contains 20 mg of bilastine
Other ingredients (inactive ingredients)	Microcrystalline cellulose, sodium starch glycolate, colloidal silicon dioxide and magnesium stearate

What Labixten Meltlets contains

Active ingredient (main ingredient)	Each meltlet contains 10 mg of bilastine
Other ingredients (inactive ingredients)	Mannitol, croscarmellose sodium, sodium stearyfumarate, sucralose and red grape flavour
Potential allergens	Sucralose



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For further information or the most up-to-date version of this leaflet visit www.labixten.co.nz

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