PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

ILAXTEN 20 mg tablets

Bilastine

Sugar free.

Read all of this leaflet carefully because it contains important information for you.

ILAXTEN is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to take ILAXTEN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ILAXTEN with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet

1. What ILAXTEN is and what it is used for
2. What you need to know before you take or give ILAXTEN
3. How to take or give 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 bilastine which is an antihistamine. ILAXTEN is used to relieve the symptoms of hay fever (sneezing, itchy, runny, blocked nose and red and watery eyes) and other forms of allergic rhinitis. It may also be used to treat itchy skin rashes.

2. What you need to know before you take or give ILAXTEN

Do not take or give ILAXTEN:

If you or a child in your care is hypersensitive (allergic) to bilastine or any of the other ingredients of ILAXTEN listed in section 6 of this leaflet.

Warnings and precautions:

Take special care with ILAXTEN:

If you or a child in your care has kidney problems and is taking other medicines (see Other medicines and ILAXTEN).

Children and adolescents:

Do not give ILAXTEN to children under 12 years of age.

Other medicines and ILAXTEN:

Always tell your health care provider if you are taking or are giving a child in your care any other medicines. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you or a child in your care is currently taking:

- ketoconazole (used to treat fungal infections)
- erythromycin (an antibiotic used to treat bacterial infections)
- ciclosporin (used to prevent organ rejection after a transplant)
- ritonavir (used to treat human immunodeficiency virus [HIV] and acquired immune deficiency syndrome [AIDS])
- diltiazem (used to treat high blood pressure and angina [chest pain])
- rifampicin (an antibiotic used to treat tuberculosis).

ILAXTEN with food and drink:

Do not take or give ILAXTEN with food or with grapefruit juice, as this will decrease the effect of

ILAXTEN. To avoid this, you can:

- take or give ILAXTEN and wait for one hour before taking or giving food or grapefruit juice, or
- if you or a child in your care has taken food or grapefruit juice, wait for two hours before taking or giving ILAXTEN.

Pregnancy and breastfeeding:

Safety during pregnancy and breastfeeding has not been established. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ILAXTEN.

Driving and using machines:

It is not always possible to predict to what extent ILAXTEN may interfere with your daily activities. ILAXTEN can cause drowsiness and dizziness. If this happens, do not drive a vehicle, use machines or do anything that requires mental alertness until the drowsiness and dizziness wear off.

3. How to take or give ILAXTEN

Do not share your medicines with any other person.

Always take or give ILAXTEN exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults, including elderly patients and adolescents aged 12 years and over:

The usual dose is one tablet (20 mg) daily. The tablet is for oral use.

Swallow your tablet with a glass of water on an empty stomach.

Take the daily dose in one single intake. The score line is not intended to divide the tablet into equal doses. It can be used to break the tablet and make swallowing easier.

If you have the impression that the effect of ILAXTEN is too strong or too weak, tell your doctor or

pharmacist.

If you take or give more ILAXTEN than you should:

In the event of overdosage, or if a child accidentally swallows some, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. Take along any tablets that are left, including the carton, so that the hospital staff can easily tell what you or a child in your care has taken.

If you forget to take or give ILAXTEN:

Do not take or give a double dose to make up for the forgotten individual doses.

4. Possible side effects

ILAXTEN can have side effects.

Not all side effects reported for ILAXTEN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ILAXTEN, please consult your doctor, pharmacist or health care provider for advice.

If any of the following happens to you or a child in your care, stop taking or giving ILAXTEN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash, hives or itching
- fainting.

These are all very serious side effects. If you or a child in your care has them, it may be because of a serious reaction to ILAXTEN. You or a child in your care may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if

you notice any of the following:

- changes in the way your heart beats (such as irregular or faster heartbeats)
- palpitations (fast or irregular heartbeats).

These are all serious side effects. You or a child in your care may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headaches
- drowsiness.

Less frequent side effects:

- cold sores (oral herpes)
- increased appetite
- feeling anxious
- difficulty falling and staying asleep
- dizziness
- ringing in the ears
- vertigo (sensation of spinning or swaying)
- dyspnoea (difficulty in breathing)
- dry or uncomfortable nose
- stomach pain or discomfort, nausea (feeling sick), diarrhoea, indigestion
- dry mouth, thirst
- feeling tired or weak
- fever
- blood tests which show changes in the way your kidneys or liver is working
- increased fat levels when blood tests are done
- increased body mass.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get 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 via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SHAPRA website.

By reporting side effects, you can help provide more information on the safety of ILAXTEN.

5. How to store ILAXTEN

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ILAXTEN contains:

The active substance in ILAXTEN is bilastine.

ILAXTEN contains 20 mg bilastine.

The other ingredients are:

Colloidal anhydrous silica

Magnesium stearate

Microcrystalline cellulose

Sodium starch glycolate (type A).

What ILAXTEN looks like and contents of the pack:

Oval, biconvex, scored, white tablets.

No lines or cracks on tablet surface.

Aluminium/aluminium blister strips in a carton containing 10 or 20 tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration:

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This leaflet was last revised in:

25 June 2025

Registration number:

52/5.7.1/0120

Date of registration:

19 April 2022

Access to corresponding Professional Information:

Request via the email address: info@menarini.co.za