

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

ILAXTEN ODT 10 mg orodispersible tablets

Bilastine

Contains sugar (131 mg mannitol) and sweetener (0,30 mg sucralose)

Read all of this leaflet carefully before your child starts taking this medicine because it contains important information for you.

ILAXTEN ODT is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to take ILAXTEN ODT carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- ILAXTEN ODT is for your child. Do not share ILAXTEN ODT with any other person.
- Ask your pharmacist if you need more information or advice.

What is in this leaflet

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- 1. What ILAXTEN ODT is and what it is used for**

ILAXTEN ODT contains bilastine which is an antihistamine (a type of medicine used to treat a condition caused by a reaction to particular substances). ILAXTEN ODT 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 (hives or urticaria).

ILAXTEN ODT 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 ODT

Do not use ILAXTEN ODT:

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

Warnings and precautions

Take special care with ILAXTEN ODT:

Talk to your doctor or pharmacist before using ILAXTEN ODT if your child has moderate or severe renal or hepatic impairment (condition in which the kidneys or the liver are not working well) or if your child is taking other medicines (see **Other medicines and ILAXTEN ODT**).

Children

Do not give ILAXTEN ODT to children under 6 years of age with a body weight below 20 kg since no sufficient data are available.

Other medicines and ILAXTEN ODT:

Always tell your health care provider if your child is taking any other medicines. (This includes complementary or traditional medicines.)

Some medicines should not be taken together and others may need their doses to be altered when taken together.

Tell your doctor or pharmacist if your child is using or receiving any of the following medicines in addition to ILAXTEN ODT:

- ketoconazole (used to treat fungal infections)

- erythromycin (an antibiotic)
- diltiazem (used to treat angina (pain or tightness in the chest area))
- ciclosporin (used to reduce the activity of your immune system, thus avoiding organ transplant rejection or reducing disease activity in autoimmune and allergic disorders, such as psoriasis, atopic dermatitis or rheumatoid arthritis)
- ritonavir (used to treat human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS))
- rifampicin (an antibiotic used to treat tuberculosis).

ILAXTEN ODT with food and drink:

Do not take or give ILAXTEN ODT with food or with grapefruit juice or other fruit juices, as this will decrease the effect of ILAXTEN ODT. To avoid this, you can:

- give your child ILAXTEN ODT 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 ILAXTEN ODT.

Pregnancy and breastfeeding:

ILAXTEN ODT 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 ILAXTEN ODT.

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 ODT.

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 ILAXTEN ODT may be different. Therefore you should check how ILAXTEN ODT affects your child, before you let your child ride bicycles or drive other vehicles or operate machinery.

ILAXTEN ODT contains ethanol and sodium

ILAXTEN ODT 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 ILAXTEN ODT will not have any noticeable effects.

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

3. How to use ILAXTEN ODT

Do not share your medicines with any other person.

Always take or give ILAXTEN ODT 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.

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 (a plain 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 teaspoon of water before giving it to your child. It has to be ensured that no rest of sediment remains in the spoon.
- You should only use water for to dissolve the orodispersible tablet, 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 doctor will determine for how long your child should take ILAXTEN ODT.

If you use more ILAXTEN ODT than you should:

If your child, or anyone else, take too much ILAXTEN ODT, 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 use ILAXTEN ODT:

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.

4. Possible side effects

ILAXTEN ODT can have side effects.

Not all side effects reported for ILAXTEN ODT are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while using ILAXTEN ODT, please consult your doctor, pharmacist or health care provider for advice.

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.

These are all very serious side effects. If your child has them, it may be because of a serious reaction to ILAXTEN ODT. Your child 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 (tachycardia)
- palpitations (feeling your heartbeat).

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:

- rhinitis (nasal irritation)
- allergic conjunctivitis (eye irritation)
- headache
- stomach pain (abdominal/upper abdominal pain)

Less frequent side effects:

- eye irritation
- dizziness
- loss of consciousness
- diarrhoea
- nausea (feeling sick)
- lip swelling
- eczema

- urticaria (hives)
- fatigue

Side effects that may be experienced in adults and adolescents are:

Frequent side effects:

- headache
- drowsiness

Less frequent side effects:

- cold sores (oral herpes)
- increased appetite
- feeling anxious
- difficulty falling and staying asleep
- dizziness
- tinnitus (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, gastritis
- dry mouth, thirst
- feeling tired or weak
- fever
- itching
- blood tests which show changes in the way your kidneys or liver is working
- increased blood fat levels when blood tests are done
- increased body mass
- belly pain.

Side effect with a frequency unknown:

- vomiting (being sick).

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 “**6.04 Adverse Drug Reaction**

Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ILAXTEN ODT.

5. How to store ILAXTEN ODT

- Store at or below 30 °C.
- Keep the blister strip 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 ODT contains:

The active substance in ILAXTEN ODT is bilastine.

ILAXTEN ODT contains 10 mg 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 ODT looks like and contents of the pack:

ILAXTEN ODT tablets are round, slightly biconvex, white, of 8 mm diameter.

ILAXTEN ODT 10 mg orodispersible tablets are packed in aluminium / aluminium blister strips in an outer carton.

Pack sizes: 10, 20, 30 or 50 orodispersible tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration:

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