PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

ILAXTEN ORAL SOLUTION 2,5 mg/mL

Bilastine

Contains sweetener (0,5 mg/mL sucralose)

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

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

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

What is in this leaflet

1. What ILAXTEN ORAL SOLUTION is and what it is used for

2. What you need to know before you use ILAXTEN Oral Solution

3. How to use ILAXTEN ORAL SOLUTION

4. Possible side effects

5. How to store ILAXTEN ORAL SOLUTION

6. Contents of the pack and other information

1. What ILAXTEN ORAL SOLUTION is and what it is used for

ILAXTEN ORAL SOLUTION contains bilastine which is an antihistamine (a type of medicine used to treat a condition caused by a reaction to particular substances). ILAXTEN ORAL SOLUTION 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 ORAL SOLUTION is 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 ORAL SOLUTION

Do not use ILAXTEN ORAL SOLUTION:

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

Warnings and precautions

Take special care with ILAXTEN ORAL SOLUTION:

Talk to your doctor or pharmacist before using ILAXTEN ORAL SOLUTION 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 ORAL SOLUTION**).

Children

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

Other medicines and ILAXTEN ORAL SOLUTION:

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 ORAL SOLUTION:

- ketoconazole (used to treat fungal infections)
- erythromycin (an antibiotic used to treat bacterial infections)
- diltiazem (used to treat angina pectoris (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 ORAL SOLUTION with food and drink:

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

- give your child ILAXTEN ORAL SOLUTION 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 ORAL SOLUTION.

Pregnancy and breastfeeding:

ILAXTEN ORAL SOLUTION 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 ORAL SOLUTION.

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 ORAL

SOLUTION.

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

ILAXTEN ORAL SOLUTION contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

ILAXTEN ORAL SOLUTION contains ethanol and sodium

ILAXTEN ORAL SOLUTION contains up to 0,44 mg of alcohol (ethanol) in each dose (4 mL) which is equivalent to 11 mg/100 mL (0,011 % *w/v*). The amount in 4 mL of ILAXTEN ORAL SOLUTION is equivalent to less than 0,02 mL beer or 0,005 mL wine.
The small amount of alcohol in ILAXTEN ORAL SOLUTION will not have any noticeable effects.

ILAXTEN ORAL SOLUTION contains less than 1 mmol sodium (23 mg) per 4 mL, that is to say essentially sodium free.

3. How to use ILAXTEN ORAL SOLUTION

Do not share your medicines with any other person.
Always take or give ILAXTEN ORAL SOLUTION 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 (4 mL of oral solution) once daily for the relief of symptoms of allergic

rhinoconjunctivitis and urticaria.

Do not give ILAXTEN ORAL SOLUTION 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 oral solution is for oral use.
- The bottle of oral solution is provided with a child-proof cap and must be opened as follows: press the plastic screw-cap downwards and turn anti-clockwise at the same time.
- The oral solution is accompanied by a cup for dosage with a mark of 4 mL (10 mg bilastine per dosing), which will help you to dose the oral solution correctly.
- Fill the cup with 4 mL of oral solution.
- Administer directly from the cup.
- Wash the cup after use.
- You should give the oral solution 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 ORAL SOLUTION.

If you use more ILAXTEN ORAL SOLUTION than you should:
If your child, or anyone else, take too much ILAXTEN ORAL SOLUTION, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. Please remember to take ILAXTEN ORAL SOLUTION pack, including the carton, so that the hospital staff can easily tell what your child has taken.

If you forget to use ILAXTEN ORAL SOLUTION:

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 ORAL SOLUTION can have side effects.

Not all side effects reported for ILAXTEN ORAL SOLUTION are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while using ILAXTEN ORAL SOLUTION, 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 ORAL SOLUTION. 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 ORAL SOLUTION.

5. How to store ILAXTEN ORAL SOLUTION

- Store at or below 30 °C.

- The shelf life after first opening is 6 months.
- Do not use ILAXTEN ORAL SOLUTION if you notice any visible signs of particles.
- 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 ORAL SOLUTION contains:

The active substance in ILAXTEN ORAL SOLUTION is bilastine.

One millilitre of the oral solution contains 2,5 mg of bilastine.

The other ingredients are:

Betadex (E459)

Hydroxyethylcellulose

Methyl parahydroxybenzoate (E218)

Propyl parahydroxybenzoate (E216)

Sucralose (E955)

Raspberry flavour (major components: ethanol, triacetin, water, ethyl butyrate, linalyl acetate)

Hydrochloric acid (for pH-adjustment)

Sodium hydroxide (for pH-adjustment)

Water, purified.

What ILAXTEN ORAL SOLUTION looks like and contents of the pack:

Clear, colourless, slightly viscous aqueous solution of pH 3,0 – 4,0 without precipitate, with a raspberry flavour.

ILAXTEN ORAL SOLUTION is packed in an amber glass bottle (Type III glass), sealed with an aluminium screw cap, with tamper-proof closure system and LDPE liner or sealed with a

polypropylene cap, with child-proof closure and LDPE liner.

Packs include either a 15 mL or 25 mL polypropylene cup for dosage graduated at 4 mL.

Each bottle contains 120 mL oral solution.

Holder of certificate of registration:

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