PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Bilastine Tiefenbacher 10 mg orodispersible tablets

For children aged 6 to 11 years with a body weight of at least 20 kg
bilastine

Read all of this leaflet carefully before your child starts taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What [PRODUCT NAME] is and what it is used for

Bilastine Tiefenbacher contains the active substance bilastine which is an antihistamine.

Bilastine Tiefenbacher is used to relieve the symptoms of hayfever (sneezing, itchy, runny, blocked-up 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).

Bilastine Tiefenbacher 10 mg orodispersible 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 [PRODUCT NAME]

Do not use [PRODUCT NAME]
- If your child is allergic to bilastine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using [PRODUCT NAME] if your child has moderate or severe renal or hepatic impairment, low blood levels of potassium, magnesium, calcium, if your child has or had heart rhythm problems or if your child's heart rate is very low, if your child is taking medicines that may affect the heart rhythm, if your child has or had a certain abnormal pattern to his/her heart beat (known as prolongation of the QTc interval on the Electrocardiogram) which can occur in some forms of heart disease or if your child is taking other medicines (see "Other medicines and [PRODUCT NAME]").

Children
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.

Other medicines and [PRODUCT NAME]

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines, including medicines obtained without a prescription. Some medicines should not be taken together and others may need their doses to be altered when taken together.

Always inform your doctor or pharmacist if your child is using or receiving any of the following medicines in addition to [PRODUCT NAME]:

- Ketoconazole (an antifungal medicine)
- Erythromycin (an antibiotic)
- Diltiazem (to treat pain or tightness in the chest area- angina pectoris)
- Cyclosporine (to reduce the activity of your immune system, thus avoiding transplant rejection or reducing disease activity in autoimmune and allergic disorders, such as psoriasis, atopic dermatitis or rheumatoid arthritis)
- Ritonavir (to treat AIDS)
- Rifampicin (an antibiotic)

[PRODUCT NAME] with food and drink
These tablets should **not** be taken with **food or with grapefruit juice or other fruit juices,** as this will decrease the effect of bilastine. To avoid this, you can:

- give your child the tablet 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 the tablet.

Pregnancy, breast-feeding and fertility
This medicine 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 this medicine. There are no or limited amount of data from the use of bilastine in pregnant women and during breast-feeding and on the effects on fertility.

In case of pregnancy or breast-feeding, or when planning to have a baby, ask your doctor for advice before taking this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

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

[PRODUCT NAME] contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take [PRODUCT NAME]

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose in children 6 to 11 years of age with a body weight of at least 20 kg, is one 10 mg tablet once daily. 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.

- The tablet is for oral use.
- Place the tablet in the mouth of your child. It will disperse rapidly in saliva and can then be

easily swallowed.
- Alternatively, you may disperse the tablet in a teaspoon of water before giving it to your child. It has to be ensured that none of the medicine remains in the spoon.
- You should use exclusively water for dispersion, do not use grapefruit juice or any other fruit juices.
- You should give the tablet to your child one hour before or two hours after intake of food or fruit juice. See section 2, "[PRODUCT NAME] with food and drink".

As the duration of treatment depends on your child's underlying disease, your physician will determine for how long your child should take [PRODUCT NAME].

If you use more [PRODUCT NAME] than you should
If your child, or anyone else, use too much of this medicine, tell your doctor immediately or go to the emergency department of your nearest hospital. Please remember to take this medicine pack or this leaflet with you.

If you forget to use [PRODUCT NAME]

Do not give a double dose to make up for a forgotten dose.

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.

If you stop using [PRODUCT NAME]
Generally, there will be no after-effects when treatment with [PRODUCT NAME] is stopped.

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.
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.

Other side effects that may be experienced:

Common: may affect up to 1 in 10 people
- rhinitis (nasal irritation)
- allergic conjunctivitis (eye irritation)
- headache
- stomach pain (abdominal /upper abdominal pain)

Uncommon: may affect up to 1 in 100 people
- eye irritation
- dizziness
- loss of consciousness
- diarrhoea
- nausea (the feeling of being sick)
- lip swelling
- eczema
- urticaria (hives)
- fatigue

Other side effects that may be experienced in adults and adolescents which cannot be ruled out

for children:

Common: *may affect up to 1 in 10 people*
- drowsiness

Uncommon: *may affect up to 1 in 100 people*
- abnormal ECG heart tracing
- abnormal blood tests (liver, kidney or blood fat)
- increased appetite
- irregular heartbeat
- increased weight
- anxiety
- dry nose
- gastritis (inflammation of the stomach wall)
- vertigo (a feeling of dizziness or spinning)
- feeling of weakness
- thirst
- dyspnoea (difficulty in breathing)
- dry mouth
- indigestion
- itching
- cold sores (oral herpes)
- fever
- tinnitus (ringing in the ears)
- difficulty in sleeping

Frequency not known: cannot be estimated from the available data
- palpitations (feeling your heartbeat)
- tachycardia (fast heartbeat)
- vomiting

Reporting of side effects
If your child gets 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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [PRODUCT NAME]

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

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What [PRODUCT NAME] contains
- The active substance is bilastine.

Each orodispersible tablet contains 10 mg of bilastine.

- The other ingredients are:

Mannitol (E 421), cellulose microcrystalline, croscarmellose sodium (see section 2 “[PRODUCT NAME] contains sodium”), magnesium aluminometasilicate, sucralose, strawberry flavour (main ingredients: maize maltodextrin, propylene glycol, gum arabic), magnesium stearate, silica colloidal anhydrous

What [PRODUCT NAME] looks like and contents of the pack

[PRODUCT NAME] 10 mg orodispersible tablets are approximately 7.5 mm, white to off-white, plain to mottled, biconvex, round tablets, debossed with ‘10’ on one side and plain on other side.

The tablets are supplied in blisters of 6, 10, 20, 30 or 50 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

[To be completed nationally]

{Name of the Member State}: {Name of the medicinal product}
{Name of the Member State}: {Name of the medicinal product}

This leaflet was last revised in
February 2025