Package leaflet: Information for the user

Ebateva 10 mg Orodispersible Tablets
Ebateva 20 mg Orodispersible Tablets
ebastine

Read all of this leaflet carefully before you start 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 you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get 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 Ebateva is and what it is used for

Ebastine is an antihistamine that helps relieve allergy symptoms such as sneezing, runny nose, watery eyes and itchy skin rashes.
In adults and children aged 12 years and older Ebateva is used to alleviate the symptoms of seasonal rhinitis (hay fever) and perennial allergic rhinitis, including cases with allergic conjunctivitis.
In adults over the age of 18 years Ebateva 10 mg is also used to alleviate itching and the development of wheals in urticaria (nettle rash).

2. What you need to know before you take Ebateva

Do not take Ebateva
- If you are allergic to ebastine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor before taking Ebateva:
- If you have low blood levels of potassium.
- If you are already taking certain antibiotics or medicines used to treat fungal infections: see "Other medicines and Ebateva" below.
- If you have severely impaired liver function (liver failure).

Ebateva can cause dry mouth. With long-term treatment, it is therefore important to have good oral hygiene (teeth should be brushed twice a day with fluoride toothpaste) to reduce the risk of tooth decay.

Children and adolescents
This medicine should only be used by children 12 years of age and over. Do not give this medicine to children under 12 as the safety and efficacy have not been established in this age group.

Other medicines and Ebateva
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Taking Ebateva and erythromycin (antibiotic) or ketoconazole, itraconazole (active substances for the treatment of fungal infections) at the same time can lead to higher blood levels of ebastine. Concomitant administration of ebastine with rifampicin (antituberculosis agent) can result in lower blood levels of ebastin and therefore reduced effects. Using Ebateva at the same time as clarithromycin or josamycin (antibiotics) is not recommended.

Ebateva with food and drink
You may take Ebateva independently from meal times.

Pregnancy, breast-feeding and fertility
There is limited experience to date of the safety in humans for the unborn child. For this reason, you should take Ebateva during pregnancy only if your doctor considers that the expected benefit outweighs the possible risks.

Do not take Ebateva if you are breast-feeding an infant, as it is not known whether the active substance passes into mother's milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Most patients treated with Ebateva may drive or carry out other activities that require a good reaction capacity. As with all other medicines, however, you should check your individual reaction after taking Ebateva before you drive or carry out complicated activities, some patients experience sleepiness or dizziness.

Ebateva contains aspartame
Ebateva 10 mg contains 2.5 mg aspartame in each tablet. Ebateva 20 mg contains 5 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Ebateva contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Ebateva 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 Ebateva

Always take 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 is:

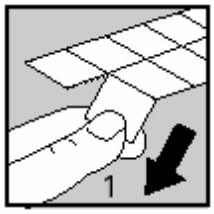
Indication	Age	Dose
Allergic rhinitis In case of severe symptoms	Children 12 years and above and adults	One Ebateva 10 mg tablet (10 mg ebastine) daily Two Ebateva10 mg tablets or one Ebateva 20 mg tablet (20 mg ebastine) once daily
Nettle rash (urticaria)	Adults above 18 years of age	One Ebateva 10 mg tablet (10 mg ebastine) once daily

In patients with impaired kidney function, no dose adjustment is necessary.

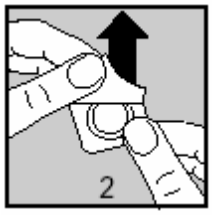
In patients with mild to moderately impaired liver function, no dose adjustment is necessary.

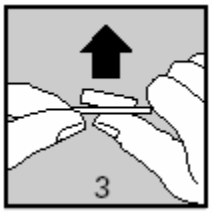
There is no experience with doses over 10 mg in patients with severe hepatic insufficiency; therefore the dose should not exceed 10 mg in these patients.

Do not push the tablet out of the pocket, as this will crush it.
Each strip contains tablets separated in pockets by perforations. Tear off one tablet pocket along the dotted lines (Figure 1)



Carefully peel off the lidding foil, starting in the corner indicated by the arrow (Figures 2 and 3)





Keep your hands dry and take the tablet out of the strip.

Place the tablet on your tongue where it will disperse: no water or other fluid is required.

You may take Ebateva independently of meal times.

Your doctor will decide on the duration of use.

If you take more Ebateva than you should
There is no special antidote for the active substance ebastine.
If you suspect an overdose with Ebateva, please tell your doctor. Depending on the severity of the intoxication, he/she will initiate the appropriate measures (monitoring of vital body functions, including ECG monitoring for at least 48 hours, symptomatic treatment and gastric lavage), if necessary.

If you forget to take Ebateva
Do not take a double dose to make up for a forgotten dose.

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.

Stop taking Ebateva and contact your doctor immediately or go to the nearest hospital if the following happens:
– Serious allergic reaction causing swelling of the face, tongue or throat which may cause difficulty in swallowing or breathing.

Other side effects include:
Very common side effects may affect more than 1 in 10 people:
– Headache.

Common side effects may affect up to 1 in 10 people:
– Drowsiness.
– Dry mouth.

Uncommon side effects may affect up to 1 in 100 people
– Sore throat (pharyngitis), runny nose (rhinitis), nose bleeds.

Rare side effects may affect up to 1 in 1,000 people
– Nervousness, insomnia.
– Disturbed sense of touch, diminished sense of touch.
– Taste disorder.
– Palpitations, accelerated pulse.
– Abdominal pain, nausea, indigestion.
– Vomiting.
– Abnormal liver function test.
– Inflammation of the liver.
– Problems with the elimination of bile causing itchiness, yellowing of the skin and eyes.
– Rash, nettle rash, inflammation of the skin.
– Menstrual disorders.
– Oedema (accumulation of water in the tissues), weakness (asthenia).
– Dizziness

Very rare side effects may affect up to 1 in 10,000 people
– Wide spread rash, eczema.
– Painful menstruation.

Frequency not known: cannot be estimated from the available data
– Weight increased
– Increased appetite

Reporting of side effects
If you get 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 Ebateva

– 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 blister and carton after ‘EXP’. The expiry date refers to the last day of that month.
– Store in the original package in order to protect from light.
– 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 protect the environment.

6. Contents of the pack and other information

What Ebateva contains

– The active substance is ebastine.
Ebateva 10 mg: Each orodispersible tablet contains 10 mg ebastine.
Ebateva 20 mg: Each orodispersible tablet contains 20 mg ebastine.
– The other ingredients are cellulose microcrystalline, lactose monohydrate, maize starch, croscarmellose sodium, aspartame (E951), peppermint flavour, silica colloidal anhydrous and magnesium stearate.

What Ebateva looks like and contents of the pack

– Orodispersible tablet
– Ebastine 10 mg: White, biconvex, round tablets embossed ’E10’ on one side, plain on the other.
Ebastine 20 mg: White, biconvex, round tablets embossed ’E20’ on one side, plain on the other.
– Available in pack sizes of:
10 mg: 10, 20, 30, 40, 50, 90, 98 and 100 orodispersible tablets.
20 mg: 10, 15, 20, 30, 40, 50, 98 and 100 orodispersible tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<To be completed nationally>

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

[Name of Member States] [Name of the medicinal product]

This leaflet was last revised in 2023-09-13.

<To be completed nationally>