MODULE 1: ADMINISTRATIVE AND PRESCRIBING INFORMATION

MODULE 1.3 PRESCRIBING INFORMATION

MODULE 1.3.1 PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ebastine 10mg Orodispersible Tablets

{Ebastine}

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Ebastine Orodispersible Tablets are and what they are used for
2. Before you take Ebastine Orodispersible Tablets
3. How to take Ebastine Orodispersible Tablets
4. Possible side effects
5. How to store Ebastine Orodispersible Tablets
6. Further information

1. WHAT EBASTINE ORODISPERSIBLE TABLETS ARE AND WHAT THEY ARE USED FOR

Ebastine Orodispersible Tablets belong to a group of medicines called antihistamines.
Ebastine Orodispersible Tablets help relieve the symptoms of hay fever and other allergic conditions. The tablets contain ebastine which is an antihistamine that helps relieve allergy symptoms such as sneezing, running nose, watery eyes and hives (urticaria).

2. BEFORE YOU TAKE EBASTINE ORODISPERSIBLE TABLETS

Do not take Ebastine Orodispersible Tablets
- if you are hypersensitive (allergic) to ebastine or to any of the other ingredients of Ebastine Orodispersible Tablets.
- you have severely impaired liver function (liver failure).

Take special care with Ebastine Orodispersible Tablets

Talk to your doctor or pharmacist before you take this medicine:
- If you suffer from liver problems.
- If you suffer from kidney problems.
- If you have a heart condition (prolonged QTc syndrome) or a lowered level of potassium in your blood (this will have been measured with a blood test).

Using other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken other medicines including medicines obtained without a prescription.

In particular, if you are taking the following medicines, your doctor may want to check whether these still work well after you have started treatment with Ebastine Orodispersible Tablets:

- If you are taking an antifungal medicine e.g. ketoconazole
- If you are taking antibiotics e.g. erythromycin

Taking Ebastine Orodispersible Tablets with food and drink
Ebastine Orodispersible Tablets can be taken either with or without food or drink.

Pregnancy and breast-feeding
Limited information is available on the use of ebastine in pregnancy and while breastfeeding. For this reason, you should take ebastine during pregnancy only if your doctor considers that the expected benefit outweighs the possible risks. You should not take ebastine if you are breast feeding an infant, as it is not known whether the active substance passes into mother's milk.

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

Driving and using machines
Ebastine Orodispersible Tablets may make you feel tired and drowsy. If you feel that you are affected you should not drive or operate machinery.

Important information about some of the ingredients of Ebastine Orodispersible Tablets
Ebastine Orodispersible Tablets contain aspartame (a source of phenylalanine). May be harmful for people with phenylketonuria.

3. HOW TO TAKE EBASTINE ORODISPERSIBLE TABLETS

Always take Ebastine Orodispersible Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Allergic rhinitis
Dosage for adults and children aged 12 years and over
The usual dose is one 10mg tablet once a day. In severe cases the dosage may be increased to two 10mg tablets once a day.

Hives (urticaria)
For adults above 18 years of age, 10 mg ebastine once daily.

Children under 12 years
Not recommended for use in children under 12 years of age.

Dose for patients with liver or kidney disorders
In patients with renal insufficiency, no dose adjustment is necessary for treatment up to 5 days. In patients with mild to moderate hepatic insufficiency, no dose adjustment is necessary for treatment up to 7 days.

Method of administration
1. Do not remove Ebastine Orodispersible Tablets from the blister until you are ready to take the medicine.

2. Carefully pull the foil of the blister open with dry hands. Do not try to press the medicine through the foil, bcause the medicine will then be damaged.
3. Carefully press the medicine out of the blister.
4. Place the medicine on the tongue, where it will quickly dissolve. No water or other fluid is necessary to swallow the medicine.
5. Swallow the medicine.

Duration of treatment
Your doctor will tell you how long to continue taking Ebastine Orodispersible Tablets.

If you take more Ebastine Orodispersible Tablets than you should
If you take more Ebastine Orodispersible Tablets than you should, contact your doctor or pharmacist immediately. Take the leaflet and your tablets with you. Depending on the severity of poisoning, your doctor, if necessary may take appropriate measures (control of the vital body functions, including ECG monitoring for 24 hours, symptomatic treatment and the emptying of the stomach). Symptoms concerning the CNS may indicate intensive care.

If you forget to take Ebastine Orodispersible Tablets
If you forget to take a dose, do not take an extra dose to make up for the forgotten dose, but take your next dose when it is due and continue as normal.
Do not take a double dose to make up for a forgotten tablet.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ebastine Orodispersible Tablets can cause side effects, although not everybody gets them.

The side effects reported in relation to use of Ebastine Orodispersible Tablets are stated below. The undesirable effects are classified as very common (occurring in more than 1 in 10 treated patients), common (occurring in more than 1 in 100 to less than 1 in 10 treated patients), uncommon (occurring in more than 1 in 1,000 to less than 1 in 100 treated patients), rare (occurring in more than 1 in 10,000 to 1 in 1,000 treated patients), very rare (occurring in less than 1 in 10,000 treated patients), and not known (cannot be estimated from the available data)..

Psychiatric disorders
- Very rare: general nervousness
  Uncommon: Insomnia

Nervous system disorders
- Common: drowsiness, headache
- Very Rare: reduced or increased sensitivity of the skin (dysaesthesia)
- Uncommon: dizziness

Cardiac disorders
- Very rare: heart palpitations, accelerated heart rate (tachycardia)

Respiratory, thoracic and mediastinal disorders
- Uncommon: Pain in the throat (pharyngitis), runny nose (rhinitis), nosebleeds

Gastrointestinal disorders

- Common: dry mouth
- Uncommon: heartburn (dyspepsia), nausea, abdominal pain
- Very rare: vomiting

Hepatobiliary disorders
- Very rare: abnormal values in a liver function test

Skin and subcutaneous tissue disorders
- Very rare: skin rash, skin rash generally with severe itching and formation of hives (urticaria), inflammation of the skin (dermatitis)

Reproductive system and breast disorders
- Very rare: menstrual disturbances

General disorders and administration site conditions
- Uncommon: dizziness, weakness (asthenia), difficulty in sleeping Very rare: accumulation of fluid

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE EBASTINE ORODISPERSIBLE TABLETS

This medicinal product does not require any special storage conditions.
Keep out of the reach and sight of children.

Do not use after the expiry date which is stated on the carton and blisters.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Ebastine Orodispersible Tablets contain

The active substance is ebastine.

The tablets also contain the following inactive ingredients: mannitol (E421), aspartame (E951), crospovidone (E1202), silicon dioxide (E551), magnesium stearate (E572) and peppermint flavour (powdarome peppermint premium and maltodextrine (maize), acacia gum (E141)/Arabic gum, pulegone).

What Ebastine Orodispersible Tablets look like and contents of the pack

Ebastine Orodispersible Tablets are orodispersible tablets (a medicine which disintegrates easily and dissolves when placed on the tongue).
The tablets are white to off white, circular, flat face beveled edge uncoated tablets plain on both faces.

Ebastine Orodispersible Tablets are packaged in Alu-Alu blisters or PVC/PE/PVdC-Aluminium blisters containing 7, 10, 14, 20, 28, 30, 50 or 100 tablets and HDPE bottles with a screw cap containing 100 tablets. Not all pack sizes may be marketed.

BROWN & BURK UK LTD
MODULE 1 ADMINISTRATIVE AND PRESCRIBING INFORMATION
MODULE 1.3 PRODUCT INFORMATION
EBASTINE, 10mg, ORODISPERSIBLE TABLETS

Marketing Authorisation Holder and Manufacturer

Brown & Burk UK Ltd
5 Marryat Close
Hounslow West
Middlesex
TW4 5DQ
UK.

This medicinal product is authorised in the Member States of the EEA under the following names

NL – Ebastine BB 10 mg orodispergeerbare tabletten
ES – Ebastina Brown 10 mg comprimidos bucodispersables
FR – Ebastine Brown & Burk 10 mg, comprimé orodispersible

This leaflet was last approved in