

Ebastimin 10 mg film-coated 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.

What is in this leaflet:

1. What Ebastimin is and what it is used for
2. What you need to know before you take Ebastimin
3. How to take Ebastimin
4. Possible side effects
5. How to store Ebastimin
6. Contents of the pack and other information

1. What Ebastimin is and what it is used for

Ebastimin belongs to a group of drugs called antihistamines (or anti-allergic agents).

Ebastimin is indicated for treatment of the symptoms of allergic processes such as seasonal or perennial allergic rhinitis associated or not associated with allergic conjunctivitis (with runny nose, itchy nose, itchy eyes, tearing, sneezing), chronic urticaria and allergic dermatitis.

2. What you need to know before you take Ebastimin

Do not take Ebastimin

- if you are allergic to ebastine or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Ebastimin.

This drug must be used with caution:

- if the results of your ECG show any alterations (QT interval prolongation).
- if you have altered levels of potassium in the blood.
- if you have a severe liver condition (see section “How to take Ebastimin”).
- if you are undergoing treatment with a type of medicine used to treat fungal infections called azole antifungals or with other drugs used to treat certain infections, called antibiotic macrolides (see section “Other medicines and Ebastimin”).
- if you are under treatment with rifampicin, a type of medicine used to treat tuberculosis.

Do not use this medicine if you experience an emergency acute allergic process, since ebastine (the active ingredient of this drug) takes 1 to 3 hours to take effect.

Children

Ebastimin 10 mg tablets must not be administered to children under 12 years of age.

Other medicines and Ebastimin

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

Some medicines can interact with Ebastimin; in these cases, it may be necessary to change the dose or stop treatment with some of the medicines:

- Ebastimin may increase the effects of other medicines used to treat allergy (antihistamines).
- Ebastimin must be used with caution in patients receiving treatment with ketoconazole and itraconazole, which are used to treat fungal infections, or with the antibiotic erythromycin, which is used to treat certain infections (as they might caused altered ECG results).
- The antihistamine effect of Ebastimin may be decreased in patients receiving treatment with rifampicin, a drug used for the treatment of tuberculosis.

No interactions have been described between ebastine and theophylline, warfarin, cimetidine, diazepam and alcohol.

Interferences with diagnostic tests

Ebastimin can interfere with the results of skin allergy tests. It is therefore advisable not to perform such tests until 5-7 days after stopping the treatment.

Ebastimin with food and drink

The tablets can be taken with or without food.

Pregnancy and breast-feeding

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.

Pregnancy

There is no experience with treatment in pregnant women. It is therefore advisable to consult a doctor before taking Ebastimin during pregnancy. They will decide whether or not the treatment must be started.

Breast-feeding

It is not known whether this medicine is excreted in breast milk. Therefore, it should not be used while breast-feeding.

Driving and using machines

In humans, no effects have been observed upon psychomotor function or on the ability to drive or use machines, at the recommended therapeutic doses. However, since the side effects include drowsiness and dizziness, take note of your response to the medication before driving or using machines.

3. How to take Ebastimin

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

Remember to take your medicine.

Your doctor will indicate the duration of your treatment with Ebastimin.

Ebastimin 10 mg film-coated tablets is not suitable for administering doses of less than 10 mg of ebastine, or for patients who have problems swallowing.

Posology

Use in adults and children over 12 years of age: The recommended dose is 1 tablet (10 mg ebastine) once daily.

Use in patients with severe liver conditions: Do not exceed a dose of 10 mg ebastine (1 tablet) per day.

Method of administration

This medicine is meant for oral administration.

The tablets can be taken with or without food, with a glass of water.

If your think the effects of Ebastimin are too strong or too weak, tell your doctor or pharmacist.

If you take more Ebastimin than you should

In case of overdose or accidental ingestion, notify your doctor or pharmacist immediately, specifying the medicine and the amount ingested, or go to your nearest hospital. Bring any tablets you have left, the container and the full

box so the healthcare professionals can identify the drug you have taken more easily.

Treatment for ebastine overdose consists of gastric pumping (lavage) and the administration of appropriate medication.

If you forget to take Ebastimin

Do not take a double dose to make up for a forgotten dose. Take the forgotten dose when you remember to do it and then keep to your usual schedule. However, if there are only a few hours left before your next dose, do not take the forgotten dose. Wait until the next day and take your dose as per your usual schedule.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Ebastimin can cause side effects, although not everybody gets them.

Clinical trials and post-marketing experience have shown the following adverse effects:

Very common (may affect more than 1 in 10 people):

- Headache

Common (may affect up to 1 in 10 people):

- Drowsiness
- Dry mouth

Rare (may affect up to 1 in 1000 people):

- Hypersensitivity reactions: allergic reactions (such as anaphylaxis and angioedema)
- Nervousness, insomnia
- Dizziness, decreased sense of touch or sensitivity, decreased or altered sense of taste
- Palpitations, tachycardia
- Abdominal pain, vomiting, nausea, digestive problems
- Liver inflammation (hepatitis), cholestasis, abnormal liver function tests (increased transaminases, gamma-GT, alkaline phosphatase and bilirubin)
- Urticaria, skin rash, dermatitis
- Menstrual disorders
- Oedema (swelling due to fluid accumulation), fatigue

Frequency not known (cannot be estimated from the available data):

- Weight gain
- Increased appetite

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine

5. How to store Ebastimin

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the container after “EXP”. The expiry date refers to the last day of that month.

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 Ebastimin contains

The active substance is ebastine. Each tablet contains 10 mg of ebastine.

The other ingredients are:

- Core: anhydrous colloidal silica, microcrystalline cellulose, croscarmellose sodium and magnesium stearate.
- Coating: Opadry Y-1-7000 (hypromellose, titanium dioxide and Macroglol 400).

What Ebastimin looks like and contents of the pack

Ebastimin is supplied as cylindrical, biconvex, white tablets, scored on one side and with the code on the other side.

Each package contains 20 film-coated tablets (10's Blister x 2).

Marketing authorisation holder and manufacturer

Laboratorios Cinfa, S.A.
C/ Olaz-Chipi, 10 - Polígono Industrial Areta
31620 Huarte (Navarra)-Spain

This leaflet was last revised in: May 2019.

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

**Council of Arab Health Ministers
Union of Arab Pharmacists**

