

Read all of these 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

## **WHAT IS IN THIS LEAFLET**

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

### **1. What Erostin is and what it is used for**

Erostin belongs to a group of drugs known as antihistamines (antiallergics).

Erostin is indicated for the symptomatic treatment of allergic conditions such as seasonal and perennial allergic rhinitis with or without allergic conjunctivitis (runny nose, itchy nose or eyes, watery eyes, sneezing, etc.), and chronic urticaria (Erostin 10mg only).

### **2. What you need to know before you take Erostin**

#### **Don't take Ebastine**

If you are allergic to ebastine or any of the other ingredients of this medicine (included in section Product Description).

If you or your child is under 12 years of age.

#### Before you start to use it

Ask your doctor or pharmacist for advice before taking Ebastine tablets.

This medicine should be used with precaution:

- If you have a history of heart disease, cardiac discomfort or palpitations, tell your doctor.
- if you suffer from severe liver disease, tell your doctor (see "How to use Ebastine tablets").

- Ebastine tablets can cause dry mouth. At long term treatment it is therefore important to have a good mouth hygiene to prevent risk for caries (the teeth should be cleaned with fluoride containing tooth paste twice daily).

Do not use this medicine if you have a severe acute allergic reaction, as ebastine (the active substance in this medicine) takes from 1 to 3 hours to be effective.

#### *Taking other medicines*

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

- The combination of this drug with medications based on ketoconazole, itraconazole, erythromycin, clarithromycin, and josamycin is generally discouraged.
- Simultaneous administration of this drug with rifampicin (an active substance to treat tuberculosis) may result in decreased ebastine levels in the blood and reduced antihistamine effects.

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

#### Taking Ebastine tablets with food and drink

The tablets can be taken with or without food.

#### Pregnancy and lactation

If you are pregnant or breast-feeding, think you might be pregnant or plan to become pregnant, consult your doctor or pharmacist before using this medicine.

#### *Pregnancy*

Due to insufficient data to ensure the perfect safety of this drug when administered during pregnancy, its use is not recommended in pregnant women.

#### *Breast-feeding*

It is not known whether the drug passes into human milk, and therefore it is not recommended for women who are breast-feeding.

#### ***Ebastine contains lactose***

Contact your doctor before taking this medicine the doctor has told you that you cannot tolerate certain sugars.

### **3. How to take Erostin**

**Use in adults and children over the age of 12:** Allergic Rhinitis: The usual dose is 10 mg of ebastine once daily. In the event of severe symptoms, the dose may be increased to 20 mg once daily. Chronic Urticaria: The usual dose is 10 mg of ebastine once daily.

**Use in patients with severe liver disease:** Do not exceed the dose of 10 mg of ebastine a day. Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Remember to take your medicine.

#### When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue using Ebastine tablets for as long as your doctor recommends.

Your doctor will indicate the duration of your treatment with Ebastine tablets.

- If you forget to use it

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

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

- **If you use too much (overdose)**

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

#### **While you are using it**

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Ebastine tablets.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Ebastine tablets to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

#### *Driving and using machines*

In humans, no effects have been observed on psychomotor function or the ability to drive or use machines at the recommended therapeutic doses.

However, it is recommended to know individual reactions before driving or performing activities requiring special attention: risk of drowsiness or dizziness.

#### **4. Possible side effects**

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

In clinical trials and post-marketing experience, the following side effects have been observed:

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 Quincke's oedema)
- Nervousness, sleeplessness
- Dizziness, decreased feeling of touch or sensation, taste change
- Palpitations, abnormal heart rhythm
- Stomach pain, vomiting, nausea, digestive problems
- Liver problems, abnormal liver function tests (transaminases, gamma-GT, alkaline phosphatase and bilirubin increased)
- Urticaria, rash, skin inflammation
- Menstrual disorders
- Oedema (fluid retention), fatigue

Very rare (may affect up to 1 in 10,000 people)

- Severe allergic manifestation

Unknown:

- Increased appetite
- Weight Increased

#### **5. How to store Erostin**

Keep this medicine out of the reach of children.

Store below 30°C.

Do not use this medicine after the expiry.

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. Contents of the pack and other information**

### **What Erostin contains**

Active ingredient: Ebastine

The other ingredients are: Microcrystalline cellulose, Pregelatinised starch, Lactose, Croscarmellose sodium, Magnesium stearate, Hypromellose HPMC 15 CPS), Talc Titanium dioxide, Iron oxide yellow, Polyethylene glycol 6000

### **What Erostin looks like and contents of the pack,**

Light yellow colored, circular, biconvex, film-coated tablets

Blister pack of 10 tablets

### **Marketing authorization holder**

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### **Manufacturer**

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### **Date of Revision**

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