

Package leaflet: Information for the patient

[To be completed nationally] 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. See section 4.

What is in this leaflet:

1. What [To be completed nationally] 10 mg film-coated tablets is and what it is used for
2. What you need to know before you take [To be completed nationally] 10 mg film-coated tablets
3. How to take [To be completed nationally] 10 mg film-coated tablets
4. Possible side effects
5. How to store [To be completed nationally] 10 mg film-coated tablets
6. Contents of the pack and other information

1. What [to be completed nationally] 10 mg film-coated tablets is and what it is used for

Antihistamine

[To be completed nationally] 10 mg film-coated tablets is a medicine for the treatment of allergic reactions.

[To be completed nationally] 10 mg film-coated tablets is used for:

- alleviation of the symptoms of seasonal rhinitis (hay fever) and perennial allergic rhinitis, including cases with allergic conjunctivitis.
- alleviation of itching and development of weals in urticaria (nettle rash) of unclear origin.

2. What you need to know before you take [to be completed nationally] 10 mg film-coated tablets

Do not take [To be completed nationally] 10 mg film-coated tablets

- if you are allergic to ebastine or any of the other ingredients of this medicine (listed in section 6).
- [To be completed nationally] 10 mg film-coated tablets should not be used for the treatment of urticaria in adolescents below the age of 18 years, and should not be used in children below 12 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking [To be completed nationally] 10 mg film-coated tablets.

Take special care with [To be completed nationally] 10 mg film-coated tablets:

- if you have low blood levels of potassium;

- in case of certain ECG alterations (known prolongation of the QTc interval on the ECG), which can occur in some forms of heart disease;
- in case of concomitant use of certain antibiotics (macrolide antibiotics such as erythromycin) or medicines used to treat fungal infections (azole antifungal agents such as ketoconazole);
- if you have severely impaired liver function (liver failure).

Other medicines and [To be completed nationally] 10 mg film-coated tablets

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

Concomitant administration of [To be completed nationally] 10 mg film-coated tablets and erythromycin (antibiotic) or ketoconazole (active substance for the treatment of fungal infections) can lead to higher blood levels of ebastine.

[To be completed nationally] 10 mg film-coated tablets with food and drink

[To be completed nationally] 10 mg film-coated tablets can be taken independently of meal times.

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.

There is no experience to date of the safety in humans for the unborn child. For this reason, you should take [To be completed nationally] 10 mg film-coated tablets during pregnancy only if your doctor considers that the expected benefit outweighs the possible risks.

Do not take [To be completed nationally] 10 mg film-coated tablets if you are breast-feeding an infant, as it is not known whether the active substance passes into mother's milk.

Driving and using machines

Most patients treated with [To be completed nationally] 10 mg film-coated tablets 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 [To be completed nationally] 10 mg film-coated tablets before you drive or carry out complicated activities.

3. How to take [to be completed nationally] 10 mg film-coated tablets

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

The recommended dose is:

Indication	Age	Dose
Allergic rhinitis	children 12 years and above and adults	1 film-coated tablet (equivalent to 10 mg ebastine) daily
In case of severe symptoms		2 film-coated tablets (20 mg ebastine) once daily
In perennial allergic rhinitis	children 12 years and above and adults	1 - 2 film-coated tablets (10 - 20 mg ebastine) once daily

Indication	Age	Dose
Nettle rash (urticaria):	adults above 18 years of age	1 film-coated tablet (10 mg ebastine) once daily

Patients with impaired kidney function:

In patients with impaired kidney function, no dose adjustment is necessary for treatment up to 5 days.

Patients with impaired liver function:

In patients with mild to moderately impaired liver function, no dose adjustment is necessary for treatment up to 7 days.

A dosage of 10 mg daily should not be exceeded in patients with severely impaired liver function.

The tablet can be divided into equal doses. Take [To be completed nationally] 10 mg film-coated tablets unchewed with liquid. [To be completed nationally] 10 mg film-coated tablets can be taken independently of meal times.

The doctor decides on the duration of use.

If you think that the effect of [To be completed nationally] 10 mg film-coated tablets is too strong or too weak, tell your doctor.

If you take more [To be completed nationally] 10 mg film-coated tablets than you should

There is no special antidote for the active substance ebastine.

If overdose with [To be completed nationally] 10 mg film-coated tablets is suspected, please tell your doctor. Depending on the severity of intoxication, he/she will initiate the appropriate measures (monitoring of vital body functions, including ECG monitoring for at least 24 hours, symptomatic treatment and gastric lavage), if necessary.

If you forget to take [To be completed nationally] 10 mg film-coated tablets

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

If you stop taking [To be completed nationally] 10 mg film-coated tablets

If you interrupt or prematurely discontinue the treatment, you must expect that the typical symptoms of the disorder will soon reappear.

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.

The following side effects have been observed during treatment with [To be completed nationally] with the following frequencies.

Common (may affect up to 1 in 10 people)

- Dry mouth
- Headache
- Drowsiness

Uncommon (may affect up to 1 in 100 people)

- Abdominal pain
- Nausea
- Epigastric symptoms (dyspepsia)

- Weakness (asthenia)
- Inflammation of the pharyngeal mucosa (pharyngitis)
- Rhinitis
- Dizziness
- Insomnia
- Nosebleeds

Not known (frequency cannot be estimated from the available data)

- Palpitations, accelerated pulse
- Sinusitis
- Vomiting
- Oedema (accumulation of water in the tissues)
- Increased liver parameters in the blood
- Disturbed sense of touch
- General nervousness
- Menstrual disorders
- Rash, nettle rash, eczema, dermatitis

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 [to be completed nationally] 10 mg film-coated tablets

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/blister after Exp. The expiry date refers to the last day of that month.

Do not store above 25° C.

Store in the original package in order to protect from light.

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

6. Content of the pack and further information

What [To be completed nationally] 10 mg film-coated tablets contains

The active substance is:

One film-coated tablet contains 10 mg Ebastine.

The other ingredients are:

Tablet core:

Cellulose, microcrystalline; sodium starch glycolate (type A); silica, colloidal, anhydrous; magnesium stearate

Tablet film:

Hypromellose; titanium dioxide; Macrogol 400

What [To be completed nationally] 10 mg film-coated tablets look like and contents of the pack

[To be completed nationally] 10 mg film-coated tablets are white to off-white, round, bevelled film-coated tablets with a score line on one side and a diameter of 7.1 mm.

Alu-PVC/PVDC blister

Original pack of 10 film-coated tablets

Original pack of 15 film-coated tablets

Original pack of 20 film-coated tablets

Original pack of 30 film-coated tablets

Original pack of 50 film-coated tablets

Original pack of 100 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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

Belgium	Ebastine Teva 10 mg comprimés pelliculés/filmomhulde tabletten/Filmtabletten
Finland	Kestox 10 mg kalvopäällysteinen tabletti
Germany	Ebastin Lindopharm 10 mg Filmtabletten
Norway	Ebastin Orifarm 10 mg dragerte tabletter
Sweden	Ebastin Orifarm 10 mg filmdragerade tabletter

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