

**Package leaflet: Information for the user**

NOTAXO 10 mg orodispergeerbare tabletten

NOTAXO 20 mg orodispergeerbare tabletten

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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

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

**1. What NOTAXO is and what it is used for**

NOTAXO 10 mg 20 mg is a medicine that is used for the treatment of allergies (antihistamine). It helps you to control the symptoms of an allergic reaction.

It is indicated in adults and children aged 12 years and older for the treatment of seasonal and persistent allergic rhinitis (runny nose), with or without allergic conjunctivitis (inflammation of the eye), and for the treatment of urticaria (hives) in adults over the age of 18 years.

**2. What you need to know before you take NOTAXO**

**DO NOT take NOTAXO**

- 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, pharmacist or nurse before taking NOTAXO:

- if you have a certain abnormal pattern to your heart beat (known prolongation of the QTc interval on the ECG) which can occur in some forms of heart disease
- if you have low potassium levels in your blood.
- if you are already taking certain antibiotics or medicines used to treat fungal infections: see “Other medicines and NOTAXO below.

- if you suffer from a severe impairment of your liver function.

#### **Children and adolescents**

- NOTAXO should not be given to children under the age of 12 years as the safety and efficacy have not been established in this age group.
- NOTAXO should not be used for the treatment of urticaria (hives) in patients under the age of 18 years as the safety and efficacy have not been established in this age group.

#### **Other medicines and NOTAXO**

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

NOTAXO can affect or be affected by some medicines which contain the following active substance:

- certain antimycotics (medicines used to treat fungal infections) like ketoconazole and itraconazole,
- or certain macrolide antibiotics (medicines used to treat bacterial infections) like erythromycin,
- or rifampicin (medicine used to treat tuberculosis).

#### **NOTAXO with food and drink**

- You can take NOTAXO 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 the use of ebastine in pregnant women.
- Therefore NOTAXO should not be used during pregnancy unless the doctor decides otherwise.

##### *Breast-feeding*

- It is not known whether ebastine is excreted in human breast milk.
- Therefore NOTAXO should not be used during breast-feeding.

#### **Driving and using machines**

- Normally NOTAXO does not have any influence on your ability to drive or use machines.
- In very rare cases, drowsiness and fainting have been reported. If you feel tired while taking this medicine do not drive or use any tools or machines.

#### **NOTAXO contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per orodispersible tablet, that is to say essentially ‘sodium-free’.

### **3. How to take NOTAXO**

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**Module 1.3.1.4      Package Leaflet – English version**

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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:

For the treatment of allergic rhinitis (runny nose) with or without allergic conjunctivitis (inflammation of the eye)

For adults and adolescents aged 12 years and older:

- 10 mg ebastine (1 NOTAXO 10 mg orodispersible tablet) once daily. In cases of severe symptoms the dose may be increased to 20 mg ebastine (2 NOTAXO 10 mg orodispersible tablets) once daily.
- 10 mg ebastine (1 NOTAXO 10 mg orodispersible tablet) once daily. In cases of severe symptoms the dose may be increased to 20 mg ebastine (1 NOTAXO 20 mg orodispersible tablet) once daily.

**Urticaria (Hives)**

Adults aged 18 years and older:

- 10 mg ebastine (1 NOTAXO 10 mg orodispersible tablet) once daily.

**Use in children and adolescents**

NOTAXO should not be given to children under the age of 12 years.

NOTAXO should not be used for the treatment of urticaria (hives) in patients under the age of 18 years.

**Patients with kidney impairment**

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

**Patients with severe liver impairment**

The dose should not exceed 10 mg in these patients.

**Patient with mild to moderate liver impairment**

In patients with mild to moderate liver impairment, no dose adjustment is necessary.

**Method of administration**

- The orodispersible tablet should be placed on the tongue where it will disperse. No water or other fluid is required but if you wish, you may drink a glass of water or another beverage after taking the tablet.
- The orodispersible tablet should be taken out of the blister carefully with dry hands and without crushing it and must be taken straightaway.

**Duration of administration**

Your doctor will decide how long you have to take NOTAXO

**If you take more NOTAXO than you should**

- If you have taken too many tablets of NOTAXO inform your doctor immediately or go to the nearest hospital or emergency department. Your doctor will decide what to do. Monitoring of vital functions, including electrocardiographic monitoring for at least 24 hours, and treatment of your complaints may be necessary.
- Intensive care may be required if you experience central nervous symptoms.

**If you forget to take NOTAXO**

Do not take a double dose to make up for a forgotten tablet. Take your next tablet at the usual time.

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.

**Very common (may affect more than 1 in 10 users)**

- Headache.

**Common (may affect up to 1 in 10 users)**

- Sleepiness.
- Dry mouth.

**Rare (may affect up to 1 in 1,000 users)**

- Allergic reactions (such as anaphylaxis and angioedema).
- Nervousness, Sleeplessness.
- Dizziness, altered sensation such as pins and needles (hypoesthesia), altered taste (dysgeusia).
- Fast heartbeat (tachycardia), unpleasant awareness of your own heartbeat (palpitations).
- Nausea, belly pain, vomiting, dyspepsia.
- Hepatitis, cholestasis, abnormal liver function test (transaminases, gamma-GT, alkaline phosphatase and bilirubin increased).
- Skin rash and hives (urticaria), rash, inflammation of the skin (dermatitis).
- Unregular period.
- Oedema, weakness.

**Not known (frequency 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 NOTAXO**

This medicinal product does not require any special storage condition.

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 or blister. 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 NOTAXO contains

- The active substance is ebastine. Each orodispersible tablet contains 10 mg 20 mg ebastine.
  - The other ingredients are: hypromellose (E464), povidone (E1201), poloxamers, gelatin, carmellose calcium, crospovidone (E1202), mannitol (E421), microcrystalline cellulose (E460), croscarmellose sodium (E468), colloidal hydrated silica (E551), trusil peppermint special\*, neotame (E961), magnesium stearate (E572).
- \* Composition: natural flavouring, nature identical flavouring, acacia gum (E414), maltodextrin, sodium benzoate (E211), butylated hydroxyanisole (E320).

### What NOTAXO looks like and contents of the pack

NOTAXO 10 mg are white to off white, round shaped, flat faced bevel edged orodispersible tablets approximately 8.50 mm in diameter and 2.20 mm thickness debossed with '10' on one side and plain on the other side.

NOTAXO 20 mg are white to off white, round shaped, flat faced bevel edged orodispersible tablets approximately 11 mm in diameter and 2.70 mm thickness debossed with '20' on one side and plain on the other side.

The orodispersible tablets are packed in OPA/Alu/PVC – Paper/PET/Alu peel-off blisters.

NOTAXO 10 mg are available in packs with 20 and 30 orodispersible tablets.

NOTAXO 20 mg are available in packs with 20 and 30 orodispersible tablets.

### Marketing Authorisation Holder

[To be completed nationally]

### Manufacturer

STADA Arzneimittel AG  
Stadastrasse 2-18  
61118 Bad Vilbel  
Duitsland

Meiji Pharma Spain, S.A.  
Avda. de Madrid, 94  
28802 Alcalá de Henares (Madrid)  
España

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

The Netherlands: NOTAXO 10 or 20 mg, orodispersible tablets

Italy: EBASTINA EG 10 or 20 mg compresse orodispersibile

Spain: Ebastina Flas Stada 10 or 20 mg, comprimido bucodispersable EFG

**This leaflet was last revised in juni 2021.**