

PACKAGE LEAFLET: INFORMATION FOR THE USER

Xados

20 mg tablets

BILASTINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 Xados is and what it is used for
2. What you need to know before you take Xados
3. How to take Xados
4. Possible side effects
5. How to store Xados

1. WHAT XADOSIS AND WHAT IT IS USED FOR

Xados contains the active substance bilastine which is an antihistamine. Xados is used to relieve the symptoms of hayfever (sneezing, itchy, runny, blocked-up nose and red and watery eyes) and other forms of allergic rhinitis. It may also be used to treat itchy skin rashes (hives or urticaria).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE XADOS

Do not take Xados:

if you are allergic to bilastine or any of the other ingredients of this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before using Xados if you have moderate or severe renal impairment and in addition you are taking other medicines (see "Other medicines and Xados").

Children

Do not give this medicine to children under 12 years of age.

Do not exceed the recommended dose. If symptoms persist, consult your doctor.

Other medicines and Xados

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, please discuss with your doctor if you are taking any of the following medicines:

- Ketoconazole (an antifungal medicine)
- Erythromycin (an antibiotic)
- Diltiazem (to treat angina)
- Cyclosporine (to reduce the activity of your immune system, thus avoiding transplant rejection or reducing disease activity in autoimmune and allergic disorders, such as psoriasis, atopic dermatitis or rheumatoid arthritis)
- Ritonavir (to treat AIDS)
- Rifampicin (an antibiotic)

Xados with food, drink and alcohol

These tablets should not be taken with food or with grapefruit juice or other fruit juices, as this will decrease the effect of bilastine. To avoid this, you can:

- take the tablet and wait for one hour before taking food or fruit juice or
- if you have taken food or fruit juice, wait for two hours before taking the tablet. Bilastine, at the recommended dose (20 mg), does not increase the drowsiness produced by alcohol.

Pregnancy, breast-feeding and fertility

There are no or limited amount of data from the use of bilastine in pregnant women and during breast-feeding and on the effects on fertility.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

A study performed to establish the effect of bilastine on the ability to drive demonstrated that treatment with 20 mg bilastine does not affect the driving performance. However very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

3. HOW TO TAKE XADOS

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

The recommended dose in adults, including the older people and adolescents aged 12 years and over, is 1 tablet (20 mg) a day.

- The tablet is for oral use.
- The tablet must be taken on an empty stomach, for example in the morning prior to breakfast. You must not eat for 1 hour after taking bilastine (see section 2, “Xadoswith food, drink and alcohol”).
- Swallow your tablet with a glass of water.
- The score line is only here to help you break the tablet if you have difficulty swallowing it whole.

Regarding the duration of treatment, your physician will determine the type of disease you are suffering from and will determine for how long you should take Xados.

Use in children

Do not give this medicine to children under 12 years of age.

If you take more Xados than you should

If you, or anyone else, have taken too many Xados tablets, contact your doctor or pharmacist immediately.

If you forget to take Xados

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

If you forget to take your dose on time, take it as soon as possible, and then go back to your regular dosing 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, this medicine can cause side effects, although not everybody gets them.

Side effects that may be experienced are:

Common: may affect up to 1 in 10 people

- headache
- drowsiness

Uncommon: may affect up to 1 in 100 people 1 to 10 users in 1,000

- abnormal ECG heart tracing
- blood tests which show changes in the way the liver is working
- dizziness
- stomach pain
- tiredness
- increased appetite
- irregular heartbeat
- increased weight
- nausea (the feeling of being sick)
- anxiety
- dry or uncomfortable nose
- belly pain
- diarrhoea
- gastritis (inflammation of the stomach wall)
- vertigo (a feeling of dizziness or spinning)
- feeling of weakness
- thirst
- dyspnoea (difficulty in breathing)
- dry mouth
- indigestion
- itching

- cold sores (oral herpes)
- fever
- tinnitus (ringing in the ears)
- difficulty in sleeping
- blood tests which show changes in the way kidney is working
- blood fats increased

Frequency not known: cannot be estimated from the available data

- palpitations (feeling your heart beat)
- tachycardia (fast heart beat)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effect 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 XADOS

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 and the blisters after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 to protect the environment.