LABIXTEN 20 mg tablets

Bilastine

PHARMACEUTICAL FORM

Tablet.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20 mg of bilastine.

Excipients: Cellulose microcrystalline, sodium starch glycolate, silica colloidal, magnesium stearate of vegetable origin.

PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antihistamines for systemic use, other antihistamines for systemic use.

ATC Code: RO6AX.

Bilastine is non-sedating, long-acting histamine antagonist, with selective peripheral H_1 receptor antagonist affinity and no affinity for muscarinic receptors.

INDICATIONS

Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria.

CONTRAINDICATIONS

Hypersensitivity to the active substance bilastine or to any of the excipients.

SPECIAL PRECAUTIONS FOR USE

The recommended dose should not be exceeded. Consult the doctor if the symptoms persist.

Efficacy and safety of bilastine in children under 12 years of age have not been established.

In patients with moderate or severe renal impairment concomitant intake of bilastine with P-glycoprotein inhibitors, such as e.g. ketoconazole, erythromycin, cyclosporine, ritonavir or diltiazem, may increase plasmatic levels of bilastine and therefore increase the risk of adverse effects of bilastine. Therefore, concomitant intake of bilastine and P-glycoprotein inhibitors should be avoided in patients with moderate or severe renal impairment.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

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

Interaction with food: Food significantly reduces the oral bioavailability of bilastine by 30%.

Interaction with grapefruit juice: Concomitant intake of bilastine 20 mg and grapefruit juice decreases bilastine's bioavailability by 30%. This effect may also apply to other fruit juices. The degree of bioavailability decrease may vary between manufacturers and fruits. The mechanism responsible for this interaction is an inhibition of OATP1A2, an uptake transporter for which bilastine is a substrate. Medicinal products that are substrates or inhibitors of OATP1A2, such as ritonavir or rifampicin, may likewise have the potential to decrease plasma concentrations of bilastine.

Interaction with ketoconazole or erythromycin: Concomitant intake of bilastine 20 mg and ketoconazole or erythromycin increases bilastine AUC 2-fold and C_{max} 2-3-fold. These changes can be explained by interaction with intestinal efflux transporters, since bilastine is a substrate for P-glycoprotein and is not metabolised. These changes do not appear to affect the safety profile of bilastine and ketoconazol or erythromycin, respectively. Other medicinal products that are substrates or inhibitors of P-glycoprotein, such as cyclosporine, may likewise have the potential to increase plasma concentrations of bilastine.

Interaction with diltiazem: Concomitant intake of bilastine 20 mg and diltiazem 60 mg increases the C_{max} of bilastine by 50%. This effect can be explained by interaction with intestinal efflux transporters and does not appear to affect the safety profile of bilastine.

Interaction with alcohol: The psychomotor performance after concomitant intake of alcohol and 20 mg of bilastine is similar to that observed after intake of alcohol and placebo.

Interaction with lorazepam: Concomitant intake of bilastine 20 mg and lorazepam 3 mg for 8 days does not potentiate the depressant Central Nervous System effects of lorazepam.

SPECIAL WARNINGS

Pregnancy and lactation

Pregnancy

There are no or limited amount data on the use of bilastine in pregnant women. As a precautionary measure, it is preferable to avoid the use of bilastine during pregnancy.

Breastfeeding

The use of LABIXTEN 20 mg tablets is not recommended during breastfeeding.

Please contact your doctor if you are pregnant, are likely to become pregnant or are breastfeeding.

Consult your doctor or pharmacist before taking any medicine.

Effects on ability to drive and use machines

not affect the driving performance. However, patients should be informed that very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

Alcohol intake

Bilastine, at the recommended dose (20 mg) does not increase drowsiness caused by alcohol.

POSOLOGY AND METHOD OF ADMINISTRATION

Route of administration:

Oral use

The score line is for breaking the tablet and making swallowing easier, but not to divide it into equal doses.

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

- take the tablet and wait an hour before eating or drinking juices, or
- if you have eaten or drunk juice, wait for two hours before taking the tablet.

Adults, including the elderly and adolescents 12 years of age and over

- One tablet once daily.
- The tablet should be taken on an empty stomach.
- Drink a glass of water to help you to swallow the tablet.
- The score line is not for dividing the tablet into two equal doses. It can be used to break the tablet and make swallowing it easier.

Duration of treatment:

With regard to the duration of treatment, your doctor will determine the type of illness you have and will tell you how long you have to take LABIXTEN 20 mg tablets.

If you forget to take LABIXTEN 20 mg tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take your dose, take it as soon as possible, and then return to your normal dosage routine.

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

TREATMENT IN THE EVENT OF AN OVERDOSE

In the event of overdose or accidental ingestion, immediately consult your doctor or pharmacist.

SIDE EFFECTS

Like all medicines, LABIXTEN 20 mg tablets can produce side effects, although not everybody gets them.

The side effects it may produce are:

Common affects 1/10 users in 100: headache, drowsiness.

Uncommon affects 1/10 users in 1000: liver enzymes increased, blood creatinine increased, blood triglicerides increased, ECG abnormalities, irregular heartbeat, dizziness, tinnitus (ringing in the ears), vertigo (a feeling of dizziness or spinning), dyspnoea (difficulty in breathing), nasal dryness or nasal discomfort, stomach pain, nausea (the feeling of being sick), diarrhoea, dry mouth, indigestion, gastritis (inflammation of the stomach wall), pruritus, weight gain, abdominal pain, increased appetite, oral herpes, tiredness, thirst, fever, feeling of weakness, anxiety, difficulty in sleeping.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

HOW TO STORE LABIXTEN 20 MG TABLETS

Keep out of the reach and sight of children.

Do not use LABIXTEN 20 mg tablets 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.

Store below 30 °C.

Any unused product or waste material should be disposed of in accordance with local requirements.

DOSAGE FORMS

Each blister contains 10 tablets. The blisters are packaged in cardboard boxes.

Pack size of 20 tablets.

MARKETING AUTHORISATION HOLDER AND MANUFACTURER

FAES FARMA, S.A. - Máximo Aguirre, 14 - 48940 Leioa (Vizcaya) Spain

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