Interaction with diltiazem: Concomitant intake of bilastine 20 mg and diltiazem 60 mg increased Cmax of bilastine by Other medicinal products that are substrates or inhibitors of P-gp, such as cyclosporine, may likewise have the
These changes do not appear to affect the safety profile of bilastine and ketoconazole or erythromycin, respectively.

Bilastine at least possibly related to bilastine and reported in more than 0.1% of the patients receiving 20 mg bilastine
patients receiving placebo.

The number of adverse events experienced by patients suffering from allergic rhinoconjunctivitis or chronic idiopathic
undesirable effects

Fertility, preganncy and lactation

For urticaria the duration of treatment depends on the type, duration and course of the complaints. Treatment could be
For allergic rhinitis the treatment should be limited to the period of exposure to allergens. For seasonal allergic rhinitis

Tinnitus

System Organ Class

Metabolism and nutrition disorders

Infections and infestations

Nervous system disorders

Cardiac disorders

Gastrointestinal disorders

Respiratory, thoracic and mediastinal disorders

Blood and blood-forming organs

Musculoskeletal and connective tissue disorders

Psychiatric disorders

Uncommon (≥1/1,000 to <1/100)

Common (≥1/100 to <1/10)

Very common (≥1/10)

Pharmacokinetic and pharmacodynamic properties

The psychopharmacological properties of bilastine were investigated in healthy volunteers using a crossover design.

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

Interaction with lorazepam: Concomitant intake of bilastine 20 mg and lorazepam 3 mg for 8 days did not potentiate

Interaction with alcohol: The psychomotor performance after concomitant intake of alcohol and 20 mg bilastine was

In patients with moderate or severe renal impairment coadministration of bilastine with P-glycoprotein inhibitors, such

In patients with hepatic impairment treatment with bilastine should be avoided.

There is no clinical experience in patients with hepatic impairment. Since bilastine is not metabolized and renal

The active substance in each bilastine 20 mg tablet is bilastine hydrochloride, equivalent to 20 mg bilastine.

No dosage adjustments are required in elderly patients (see section Pharmacokinetic and Pharmacodynamic properties).

In patients under 12 years of age

No dosage adjustment is required if patients have impaired renal function.

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Posology and method of administration

Children under 12 years

Adults and adolescents (12 years of age and over)

Interactions with other medicinal products and other substances

In patients with moderate or severe renal impairment treatment with bilastine should be avoided.

In patients with hepatic impairment treatment with bilastine should be avoided.

Bilastine is excreted less in patients with renal impairment compared to healthy volunteers.

Bilastine is not metabolized by the liver. In patients with moderate or severe renal impairment there is no need for

Bilastine is a substrate of the organic anion transporting polypeptide 1A2 (OATP1A2) and is also transported by OATP2B1.

The results of this interaction are in line with the results of the OATP1A2 inhibition described in section Pharmacokinetic

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Name of the medicinal product

BILAXTEN 20 mg Tablets

Pharmaceutical form

Each tablet contains 20 mg of bilastine.

Pharmacological and therapeutical properties

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Bilastine did not induce or inhibit activity of CYP450 isoenzymes in in vitro studies.

At therapeutic doses bilastine is 84–90% bound to plasma proteins.

Bilastine presents linear pharmacokinetics in the dose range studied (5 to 220 mg), with a low interindividual variation. The mean elimination half-life calculated in healthy volunteers was 14.5 h.

In a mass balance study performed in healthy volunteers, after administration of a single dose of 20 mg 14C-bilastine, almost 95% of the administered dose was recovered in urine (28.3%) and faeces (66.5%) as unchanged bilastine, confirming that bilastine is not significantly metabolized in humans. The mean elimination half-life in healthy volunteers was 14.5 h. Bilastine, like amiodarone, exhibits a dose proportional increase in systemic exposure in humans after multiple dose administration. Following oral administration of 20 mg bilastine to elderly patients, the mean AUC(0-24) increased by 20% compared to younger subjects.

Bilastine is a non-sedating, long-acting histamine antagonist with selective peripheral H1 receptor antagonist affinity. In a clinical study in healthy volunteers, the sedation score at 4 h after a single oral dose of 20 mg bilastine was 1.6 (placebo 2.7) and at 24 h was 0.6 (placebo 1.6). In another study, sedation occurred in 1% of 186 patients treated with 20 mg bilastine and in 0% of 186 patients treated with placebo. In a study performed in elderly patients, bilastine 20 mg was associated with a sedation score of 1.7 compared with 2.2 for placebo. Bilastine is not expected to cause significant drowsiness or dizziness.

In the event of overdose symptomatic and supportive treatment is recommended.

Bilastine is a potent inhibitor of OATP1B1, OATP1B3, OATP2B1, OAT1, OAT3, OCT1, OCT2, and NTCP, since only mild inhibition was detected in vitro.

Bilastine is not expected to inhibit the following transporters in the systemic circulation: P-gp, MRP2, BCRP, BSEP, NTCP, OAT1, OAT2, OAT3, OAT4, OCT1, OCT2, OCT3, and OATP1A2.

Pharmacodynamic properties

Bilastine specifically blocks the peripheral H1 receptors. Bilastine is a non-sedating, long-acting histamine antagonist with no affinity for muscarinic receptors.

In a 14 day placebo-controlled study bilastine 20 mg, administered once daily for 14–28 days, was effective in relieving symptoms such as sneezing, runny nose, and itchy and dry throat. Patients improved their sleep conditions and their quality of life.

Elderly patients (≥ 65 years) included in phase II and III studies showed no difference in efficacy or safety with younger patients. However, caution is required in renal impaired patients.

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