SUMMARY OF PRODUCT CHARACTERISTICS
BASTIN 20 mg Tablets (Bilastine 20 mg)

1. NAME OF THE MEDICINAL PRODUCT

BASTIN 20 mg Tablets (Bilastine 20 mg Film-Coated Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 20 mg bilastine.

Excipients with known effect:

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

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

White round-shaped, standard concave film-coated tablet, plain on both sides.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Bastin is indicated for the symptomatic treatment of:

- Allergic rhinoconjunctivitis (seasonal and perennial) in adults and adolescents (12 years of age and over).
- Urticaria in adults and adolescents (12 years of age and over).

4.2 Posology and method of administration

Adults and adolescents (12 years of age and over)

20 mg bilastine (1 tablet) once daily. The tablet should be taken one hour before or two hours after intake of food or fruit juice (see section 4.5).

Duration of treatment

For allergic rhinoconjunctivitis, treatment should be limited to the period of exposure to allergens. For seasonal allergic rhinitis, treatment may be discontinued after symptom resolution and reinitiated upon reappearance. In perennial allergic rhinitis, continued treatment may be proposed during allergen exposure periods. For urticaria, duration depends on the type, duration and course of the disease.

Special populations

Elderly: No dosage adjustments required. Renal impairment: No dose adjustment required in adults. Hepatic impairment: No dose adjustment required in adult patients (bilastine is not metabolised; hepatic impairment not expected to increase systemic exposure). Children 6 to 11 years with body weight ≥20 kg: bilastine 10 mg orodispersible tablet or oral solution are appropriate. Children under 6 years of age and under 20 kg: should not use bilastine.

Method of administration

Oral. The tablet is to be swallowed with water, as a single daily intake.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Paediatric population

Efficacy and safety of bilastine in children under 2 years of age have not been established. There is little clinical experience in children aged 2 to 5 years; bilastine should not be used in these age groups.

In patients with moderate or severe renal impairment, co-administration of bilastine with P-glycoprotein inhibitors (such as ketoconazole, erythromycin, cyclosporine, ritonavir or diltiazem) should be avoided, as increased plasmatic levels of bilastine may increase the risk of adverse effects.

QT/QTc prolongation

Cases of electrocardiogram QT prolonged have been reported in patients using bilastine (see sections 4.8 and 5.1). Medicinal products that cause QT/QTc prolongation are suspected to increase the risk of Torsade de pointes. Caution should therefore be exercised when administering bilastine to patients who are at increased risk of QT/QTc prolongation, including: patients with a history of cardiac arrhythmias; patients with hypokalaemia, hypomagnesaemia, hypocalcaemia; patients with known prolongation of the QT interval or significant bradycardia; patients with concomitant use of other medicinal products associated with QT/QTc prolongation.

Sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet and is essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Food and fruit juice:

Food significantly reduces the oral bioavailability of bilastine by approximately 30%. Grapefruit juice decreases bilastine bioavailability by approximately 30% through inhibition of OATP1A2. This effect may apply to other fruit juices. 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.

Ketoconazole or erythromycin (P-gp inhibitors):

Concomitant intake increased bilastine AUC 2-fold and Cmax 2–3-fold. These changes do not appear to affect the safety profile. Other P-gp substrates or inhibitors (e.g. cyclosporine) may likewise increase bilastine plasma concentrations.

Diltiazem:

Increased Cmax of bilastine by 50%. Does not appear to affect the safety profile.

Alcohol:

Psychomotor performance after concomitant intake of alcohol and bilastine 20 mg was similar to that after intake of alcohol and placebo.

Lorazepam:

Concomitant intake of bilastine 20 mg and lorazepam 3 mg for 8 days did not potentiate the CNS depressant effects of lorazepam.

Paediatric population:

Interaction studies have only been performed in adults. As there is no clinical experience in children, the adult interaction study results should be taken into consideration when prescribing bilastine to children.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited data from the use of bilastine in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity, parturition or postnatal development. As a precautionary measure, it is preferable to avoid the use of Bastin during pregnancy.

Breast-feeding

The excretion of bilastine in human milk has not been studied. Available pharmacokinetic data in animals have shown excretion of bilastine in milk (concentrations approximately half of those in maternal plasma). A decision on whether to continue/discontinue breast-feeding or to discontinue/abstain from Bastin therapy must be made taking into account the benefit of breast-feeding for the child and the benefit of therapy for the mother.

Fertility

A study in rats did not indicate any negative effect on fertility.

4.7 Effects on ability to drive and use machines

A study performed in adults demonstrated that treatment with bilastine 20 mg did not affect driving performance. However, as the individual response may vary, patients should be advised not to drive or use machines until they have established their own response to bilastine.

4.8 Undesirable effects

Summary of safety profile — Adults and adolescents

The incidence of adverse events in adult and adolescent patients treated with bilastine 20 mg was comparable with placebo (12.7% vs 12.8%). The most commonly reported ADRs were headache, somnolence, dizziness and fatigue, each occurring with comparable frequency to placebo. Post-marketing, electrocardiogram QT prolonged has also been reported (see section 4.4). Frequency not known (post-marketing): palpitations, tachycardia, hypersensitivity reactions (including anaphylaxis, angioedema, dyspnoea, rash, localised oedema/local swelling, erythema) and vomiting.

Summary of safety profile — Paediatric population (2 to 11 years)

In a 12-week controlled clinical trial (N=260 children receiving bilastine 10 mg vs N=249 placebo), adverse drug reactions were seen in 5.8% vs 8.0% of patients, respectively. No significant differences in QTc were observed. The related ADRs most commonly reported were headache, allergic conjunctivitis, rhinitis and abdominal pain, occurring with comparable frequency to placebo.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

In clinical trials, bilastine at 10–11 times the therapeutic dose (220 mg single dose; 200 mg/day for 7 days) resulted in a two-fold higher frequency of adverse events than placebo. The most frequently reported were dizziness, headache and nausea. No serious adverse events and no significant QTc prolongation were reported. A thorough QT/QTc study (100 mg × 4 days in 30 healthy volunteers) showed no significant QTc prolongation.

There are no data for overdose in children. In the event of overdose, symptomatic and supportive treatment is recommended. There is no known specific antidote.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamines for systemic use, other antihistamines for systemic use. ATC code: R06AX29.

Bilastine is a non-sedating, long-acting histamine antagonist with selective peripheral H1 receptor antagonist affinity and no affinity for muscarinic receptors. Bilastine inhibited histamine-induced wheal and flare skin reactions for 24 hours following single doses. No clinically relevant QTc prolongation or any other cardiovascular effect has been observed in clinical trials, even at doses of 200 mg daily (10 times the clinical dose) for 7 days or when co-administered with P-gp inhibitors. Post-marketing cases of QT prolonged have been reported (see section 4.4).

In controlled clinical trials at 20 mg once daily, the CNS safety profile of bilastine was similar to placebo and the incidence of somnolence was not statistically different from placebo. Bilastine at doses up to 40 mg q.d. did not affect psychomotor performance or driving performance in clinical trials. Elderly patients (≥65 years) showed no difference in efficacy or safety compared to younger patients. A post-authorisation study in 146 elderly patients confirmed no differences in safety profile from the adult population.

Paediatric population: In a 12-week controlled clinical trial in 509 children aged 2–11 years, bilastine 10 mg (once daily) showed a safety profile similar to placebo. No significant differences in QTc were observed following 10 mg bilastine compared with placebo in these children. According to guidelines, the efficacy proved in adults and adolescents can be extrapolated to children aged 6–11 years with body weight ≥20 kg, as systemic exposure with 10 mg bilastine in this paediatric population is equivalent to the exposure with 20 mg bilastine in adults and adolescents.

5.2 Pharmacokinetic properties

Absorption

Rapidly absorbed; Tmax approximately 1.3 hours. Mean oral bioavailability 61%. No accumulation. Linear pharmacokinetics 5–220 mg.

Distribution

Bilastine is a substrate of P-gp and OATP. It does not appear to be a substrate of BCRP or renal transporters OCT2, OAT1 and OAT3. At therapeutic doses, bilastine is 84–90% bound to plasma proteins.

Biotransformation
Bilastine did not induce or inhibit CYP450 isoenzymes in vitro. Bilastine is not significantly metabolised in humans.

Elimination
Approximately 95% of the administered dose recovered as unchanged bilastine in urine (28.3%) and faeces (66.5%). Mean elimination half-life 14.5 hours.

Renal impairment
AUC increases with severity of renal impairment. These pharmacokinetic changes are not expected to have a clinically relevant influence on safety, as bilastine plasma levels in patients with renal impairment remain within the safety range.

Hepatic impairment
Bilastine is not metabolised; biliary excretion expected to be only marginally involved. Hepatic impairment not expected to have a clinically relevant influence on bilastine pharmacokinetics.

Paediatric population (6 to 11 years)
Pharmacokinetic analysis of plasma concentration data in 31 children aged 4–11 years showed that bilastine 10 mg once daily results in systemic exposure equivalent to that seen after 20 mg in adults and adolescents (mean AUC 1014 ng x hr/mL in children 6–11 years).

5.3 Preclinical safety data
Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential. In reproduction toxicity studies, effects on the foetus (pre- and post-implantation loss in rats and incomplete ossification in rabbits) were observed only at maternally toxic doses (>30-fold human exposure at NOAEL). In a lactation study, bilastine was identified in the milk of nursing rats (approximately half of those in maternal plasma). In a fertility study in rats, bilastine up to 1000 mg/kg/day did not induce any effect on female and male reproductive organs, mating, fertility or pregnancy indices.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Microcrystalline cellulose, sodium starch glycolate, aerosol-200, talcum, polacrilin potassium, magnesium stearate, Fine Coat UFC 20, titanium dioxide.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
3 years.

6.4 Special precautions for storage
This medicinal product does not require any special storage conditions. Keep out of the reach and sight of children.

6.5 Nature and contents of container
ALU-ALU blister foil in unit box alongside with package insert. Pack size: 10 tablets.

6.6 Special precautions for disposal and other handling
Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
SYMBIOTICA BIOCEUTICALS LIMITED
P.O. Box 64001-00620, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

17.12.2025

10. DATE OF REVISION OF THE TEXT

17.12.2025