PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE
BASMEDENE 20 (20 mg tablets)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
BASMEDENE 20: Each tablet contains 20 mg of bilastine.
Sugar free.
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Tablet.
White to off white, scored oval shaped tablets debossed with '2' on one side of breakline and '0'on other side of breakline on one side, plain on other side.
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS
Therapeutic indications
Symptomatic treatment of seasonal allergic rhinitis (SAR), perennial allergic rhinitis (PAR) and idiopathic chronic urticaria (ICU) in adults and adolescents (12 years and over).

Posology and method of administration
Posology
Adults and adolescents (12 years of age and over)
One tablet (20 mg) BASMEDENE 20 once daily and to be swallowed with water.
It is recommended to take the daily dose in one single intake.
BASMEDENE 20 should be taken one hour before or two hours after intake of food or fruit juice (see section 4.5).

Special populations
Elderly
No dosage adjustments are required in elderly patients (see sections 5.1 and 5.2).

Renal impairment:
No dosage adjustment is required in patients with renal impairment because, despite the increase in AUC, the concentrations of bilastine were within the therapeutic range (see section 5.2).

Hepatic impairment:
There is no clinical experience in patients with hepatic impairment. Since BASMEDENE 20 is not metabolised, hepatic impairment is not expected to increase systemic exposure above the safety margin. Therefore, no dosage adjustment is required in patients with hepatic impairment (see section 5.2).

Paediatric population
The safety and efficacy in children below 12 years have not yet been established.

Duration of treatment:
Treatment should be discontinued after the symptoms have resolved. For seasonal allergic rhinitis treatment should not exceed 14 days, while for idiopathic chronic urticaria the duration of treatment should not exceed 28 days.

Contraindications
Hypersensitivity to bilastine or to any of the excipients listed in section 6.1.

Special warnings and precautions for use
Coadministration of P-glycoprotein inhibitors and BASMEDENE 20 should be avoided in patients with moderate or severe renal impairment.

P-glycoprotein inhibitors, such as e.g., ciclosporin, erythromycin, ketoconazole, ritonavir or diltiazem, may increase plasmatic levels of BASMEDENE 20 and therefore increase the risk of adverse reactions of BASMEDENE 20 .

Interaction with other medicines and other forms of interaction

Interaction with diltiazem:
Concomitant intake of diltiazem 60 mg and BASMEDENE 20 can increase the Cmax of bilastine by 50%. This is due to the interaction with intestinal efflux transporters (see section 5.2) and should affect the safety profile of BASMEDENE 20 .

Interaction with ketoconazole or erythromycin:
Concomitant intake of ketoconazole or erythromycin with BASMEDENE 20, can increase BASMEDENE 20 AUC 2-fold and Cmax 2-3 fold. Since bilastine is substrate for P-gp and not metabolised (see section 5.2), these changes can be explained by interaction with intestinal efflux transporters. The changes do not seem to affect the safety profile of ketoconazole or erythromycin and bilastine. Other medicines that are substrates or inhibitors of P-gp, like ciclosporin may also have the potential to increase plasma concentrations of bilastine.

Interaction with lorazepam:
Concomitant intake of lorazepam 3 mg and bilastine 20 mg for 8 days did not increase the depressant CNS effects of lorazepam.

Interaction with alcohol:
The psychomotor performance after concomitant intake of BASMEDENE 20 and alcohol was found to be similar to that observed after intake of alcohol and placebo.

Interaction with grapefruit juice:
Concomitant intake of grapefruit juice and BASMEDENE 20 decreased BASMEDENE 20 bioavailability by 30%. The interaction is due to the inhibition of OATP1A2, an uptake transporter for which bilastine is a substrate (see section 5.2). Medicines that are substrates or inhibitors of OATP1A2, such as rifampicin or ritonavir, may also have the potential to decrease plasma concentrations of bilastine.

Interaction with food:
Oral bioavailability of BASMEDENE 20 is reduced by 30% when given with food.

Fertility, pregnancy and lactation
Pregnancy
BASMEDENE 20 should not be used during pregnancy. The safety of BASMEDENE 20 in pregnancy has not been established. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity, parturition or postnatal development.
There are no data for the use of bilastine, such as in BASMEDENE 20, in pregnant women.

Breastfeeding
BASMEDENE 20 should not be used during lactation or breastfeeding. The safety of BASMEDENE 20 in lactation has not been established.
It is unknown whether BASMEDENE 20 is excreted in human breast milk. The excretion of BASMEDENE 20 in milk has not been studied in animals.

Fertility
There are no or limited amount of clinical data. A study in rats did not indicate any negative effect on fertility.

Effects on ability to drive and use machines
BASMEDENE 20 can cause drowsiness or dizziness, therefore patients taking BASMEDENE 20 should not drive or use machines.

Undesirable effects
Tabulated summary of adverse reactions

MedDRA system organ class	Frequency	Adverse reactions
Infections and infestations	Less frequent	Oral herpes
Immune system disorders	Frequency unknown	Hypersensitivity reactions
Metabolism and nutrition disorders	Less frequent	Increased appetite
Psychiatric disorders	Less frequent	Anxiety, Insomnia
Nervous system disorders	Frequent	Somnolence, Headache
	Less frequent	Dizziness
Ear and labyrinth disorders	Less frequent	Tinnitus, Vertigo
Cardiac disorders	Less frequent	Right bundle branch block, Sinus arrhythmia, Electrocardiogram QT prolonged, Other ECG abnormalities
Respiratory, thoracic and mediastinal disorders	Less frequent	Dyspnoea, Nasal discomfort, Nasal dryness
Gastrointestinal disorders	Less frequent	Upper abdominal pain, Abdominal pain, Nausea, Stomach discomfort, Diarrhoea, Dry mouth, Dyspepsia, Gastritis,
	Frequency unknown	Vomiting
Skin and subcutaneous tissue disorders	Less frequent	Pruritus
General disorders and administration site conditions	Less frequent	Fatigue, Thirst, Improved pre-existing condition, Pyrexia, Asthenia
Investigations	Less frequent	Increased gamma-glutamyltransferase, Alanine aminotransferase increased, Aspartate aminotransferase increased, Blood creatinine increased, Blood triglycerides increased, Increased weight

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Overdose
The adverse reactions most frequently reported were dizziness, headache and nausea.
In the event of overdose symptomatic and supportive treatment is recommended.
There is no known specific antidote to bilastine, as in BASMEDENE 20.

5 PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
A 5.7.1 Oral Antihistaminics.
ATC code RO6AX29.
Bilastine is a non-sedating, long-acting histamine antagonist with selective peripheral H1 receptor antagonist affinity and no affinity for muscarinic receptors.

Pharmacokinetic properties
Absorption
Bilastine is rapidly absorbed after oral administration. The mean value of bilastine oral bioavailability is 61%. Time to maximum plasma concentration is around 1.3 hours with no accumulation observed.
Distribution
At therapeutic doses bilastine is 84-90% bound to plasma proteins.
Bilastine does not appear to be a substrate of the renal transporters OCT2, OAT1 and OAT3 or the transporter BCRP.
Biotransformation
Bilastine did not inhibit or induce activity of CYP450 isoenzymes in in vitro studies.
Elimination
The mean elimination half-life calculated in healthy volunteers was 14.5 h. Bilastine is not significantly metabolized in humans. 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

6 PHARMACEUTICAL PARTICULARS
List of excipients
Colloidal Anhydrous Silica
Magnesium Stearate
Microcrystalline Cellulose
Sodium Starch Glycolate

Incompatibilities
Not applicable

Shelf life
24 Months

Special precautions for storage
This medicine does not require any special storage conditions.

Nature and contents of container
Plain cold formable Alu foil – 0.025 mm Alu hard tempered foil blister pack.
Each blister strip contains 7 or 10 tablets. Blister strips are packed in cardboard boxes.
Pack sizes: 7, 10, 14, 20, 28, 30, 40, 50, 56 or 60 tablets. Not all pack sizes will be marketed.

Special precautions for disposal
No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION
Trinity Pharma (Pty) Ltd
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8 REGISTRATION NUMBER
BASMEDENE 20: 56/5.7.1/0591

9 DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION
N.A

10 DATE OF REVISION OF THE TEXT
N.A

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