SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

1.1 Product Name:

Ebastine Suspension

1.2 Strength

5mg/5ml

2. QUALITATIVE AND QUANTITAVE COMPOSITION

Each 5 ml (one teaspoonful) contains:

Ebastine BP ……..5 mg

In a flavored base

3. PHARMACEUTICAL FORM

Suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Ebastine is indicated for Symptomatic treatment of allergic conditions, such as: allergic rhinitis or conjunctivitis, both seasonal and perennial (nasal discharge, nasal itching, eye itching, weeping, sneezing, etc.), chronic urticaria and allergic dermatitis.

4.2 Posology and method of administration

Adults and children older than 12 years

Ebastine 10mg tablet or 10 ml (2 teaspoonfuls) Ebastine Syrup once daily. In severe symptoms Ebastine 20mg tablet or 20 ml Ebastine Syrup (4 teaspoonfuls) once daily

Children from 6 to 11 years old

One 5 ml dose (equivalent to Ebastine 5 mg) once daily

Children from 2 to 5 years old

One 2.5 ml dose (equivalent to Ebastine 2.5 mg) once daily

There is no need for dose adjustment in patients with mild to moderate liver function disorders.

4.3 Contraindications

Ebastine is contraindicated in patients with known hypersensitivity to the active ingredient.

4.4 Special warnings and precautions for use

Since ebastine reaches its therapeutic effect 1 to 3 hours after administration, Ebastine must not be used in urgent acute allergic cases.

Caution must be exercised when using Ebastine in patients known to be at cardiac risk such as those with long QT syndrome, hypokalemia, treatment with any drug known to produce an increase in QT interval or inhibit CYP3A4 enzyme systems such as azole antifungals and macrolide antibiotics.

4.5 Interaction with other medicinal products and other forms of interaction

The interaction of Ebastine in combination with either ketoconazole or erythromycin (both known to prolong the QTc interval) has been evaluated. Interaction has been observed with these combinations, resulting in higher ebastine plasma levels but only in about a 10 msec increase in QTc greater than the increase seen with ketoconazole or erythromycin alone.

When Ebastine is administered with food, there is a 1.5 to 2.0-fold increase in the plasma levels and the AUC of the main active acid metabolite of ebastine. This increase does not alter the Tmax. The administration of Ebastine with food does not cause a modification in its clinical effect.

4.6 Pregnancy and lactation

Pregnancy

The safety of ebastine during human pregnancy has not been established

Lactation

Ebastine should be used during pregnancy only if clearly needed. It is not known whether Ebastine is excreted in human milk, therefore, Ebastine should not be used during lactation.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

In clinical trials, the most commonly reported side effects with Ebastine were headache, dry mouth and drowsiness, which were comparable to placebo.

Other less commonly reported adverse events include: pharyngitis, abdominal pain, dyspepsia, asthenia, epistaxis, rhinitis, sinusitis, nausea and insomnia.

4.9 Overdose

In studies conducted at a high dosage; no clinically meaningful signs or symptoms were observed up to 100 mg given once daily. There is no specific antidote for Ebastine. Gastric lavage, monitoring of vital functions including ECG and symptomatic treatment should be carried out.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

In vitro and in vivo data demonstrate that Ebastine is a potent, long-lasting and highly selective histamine H1-receptor antagonist devoid of untoward CNS actions and anticholinergic effects.

Clinical : Histamine skin wheal studies have shown a statistically and clinically significant anti-histamine effect beginning at 1 hour and lasting in excess of 48 hours. After the discontinuation of the administration of a 5 day-course treatment with Ebastine, the antihistamine activity remained apparent for more than 72 hours. This activity parallels the plasma levels of the main active acid metabolite, carebastine.

After repeated administration, inhibition of the peripheral receptors remained at a constant level, without tachyphylaxis. These results suggest that Ebastine at a dose of at least 10 mg produces a rapid, intense and long-lasting inhibition of peripheral H,, histamine receptors, consistent with a once-a-day administration.

Sedation was studied through pharmaco-EEG, cognitive performance, visual-motor coordination tests and subjective estimates. There was no significant increase of sedation at

the recommended dose. These results are consistent with those from double blind clinical trials. The incidence of sedation is comparable between placebo and Ebastine.

5.2 Pharmacokinetic properties

Ebastine is rapidly absorbed and undergoes extensive first pass metabolism following oral administration. Ebastine is almost totally converted to the pharmacologically active acid metabolite, carebastine.

After a single 10 mg oral dose, peak plasma levels of the metabolite occur at 2.6 to 4 hours and achieve levels of 80 to 100 ng/ml. The half-life of the acid metabolite is between 15 and 19 hours with 66% of the drug being excreted in the urine mainly as conjugated metabolites. Following the repeated administration of 10 mg once-daily, steady state was achieved in 3 to 5 days with peak plasma levels ranging from 130 to 160 ng/ml. Both ebastine and carebastine are highly protein bound, 95%. In elderly subjects, no statistically significant changes were observed in the pharmacokinetics compared to those of young adult volunteers. In patients with renal insufficiency the elimination half-life of carebastine was increased to 23-26 hours. Similarly, in patients with hepatic insufficiency, the half-life is increased to 27 hours.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction and development. No carcinogenicity studies have been performed; however, there is no evidence to suggest carcinogenic potential.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose, Methyl Paraben, Propyl parabens, Xanthan gum, Saccharine sodium, Polysorbate-80, Colour Quinoline yellow supra & Flavour orange booster.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months from the date of manufacturing.

6.4 Special precautions for storage

Store below 30°C. Protect form light. Keep out from the reach of children.

6.5 Nature and contents of container

1 X 60 ml Bottle

6.6 Special precautions for disposal and other handling

No special requirements

7. Marketing Authorization Holder:

MICRO LABS LIMITED
31, Race course road
Bangalore-560001 INDIA

8. Marketing Authorization Numbers

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9. Date of first authorization

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10. ate of revision of the text

Dec 2019