MICRO LABS LIMITED, BANGALORE, INDIA			
1	Product Name	Ebast-DT	Colours Used
2	Strength	5 mg	BLACK
3	Component	Leaflet	
4	Category	Export - Philippines	
5	Dimension	140 (L) x 280 (H) mm	
6	Artwork Code	EXG-ML01I-1506/A	
7	Pharma Code	385	
8	Reason for Change	Size and New Regulation	

	Prepared by (DTP)	Checked by (PD)	Approved by			
			Head CQA	Head Production/ Packing (Site)	Head QC (Site)	Head QA (Site)
Sign	Kantharaju L.					
Date	12-01-2023					

Front Side

140 mm

35 mm | 35 mm | 35 mm | 35 mm | 35 mm | 35 mm | 35 mm | 35 mm

EBASTINE

EBAST-DT

5 mg Dispersible Tablet
ANTIHISTAMINE

PRODUCT NAME :
Ebast-DT

DOSAGE FORM AND STRENGTH:
Ebastine Dispersible tablets 5mg

PHARMACOLOGIC CATEGORY:
Other anti-histamines for systemic use

PRODUCT DESCRIPTION:
Orange coloured, flat, circular beveledged uncoated dispersible tablets with a breakline on one surface having pleasant odour.

FORMULATION/COMPOSITION:
Each dispersible tablet contains:
Ebastine .....5 mg

PHARMACODYNAMICS/PHARMACOKINETICS:
Pharmacodynamics:
Ebastine is a potent, highly selective antagonist of the histamine H1 receptor with prolonged effects and no anticholinergic effects.

Pharmacokinetics:
Ebastine is rapidly absorbed after oral administration. It is almost totally converted to the active metabolite carebastine. After an oral dose of ebastine, maximum plasma levels of 80 to 100 ng/ml carebastine were observed after 2.6 to 4 hours. After a single oral dose of 20 mg ebastine, mean peak plasma levels of the metabolite, carebastine of 195 ng/ml occur after 3 to 6 hours. The half-life of the metabolite is 15-19 hours, 66% of which is excreted in the urine in the form of conjugated metabolites.
After repeated administration of a daily dose of 10 mg, steady-state with plasma levels of 130-160 ng/ml is reached after 3 to 5 days.
More than 95% of both ebastine and carebastine is bound to plasma proteins.
In vitro studies on human hepatic microsomes show that ebastine is metabolised to carebastine predominantly via the CYP450 (2J2, 4F12 and 3A4) enzyme systems. After concomitant administration of ketoconazole or erythromycin (both inhibitors of CYP450 3A4) significant increases in plasma ebastine and carebastine concentrations were observed.
In elderly patients, no changes in pharmacokinetics were observed compared with young adults.
In patients with renal impairment, the elimination half-life of the metabolite, carebastine is prolonged to 23-26 hours. In patients with hepatic impairment, the half-life is 27 hours.
For ebastine film-coated tablets, in cases of concomitant food intake there is a 1.5- to 2.0-fold rise in the plasma level of carebastine, the active principal metabolite of ebastine, and a 50% increase in the AUC, while T_{max} remains unchanged. However, the clinical efficacy is not affected.

INDICATIONS:
Symptomatic treatment of seasonal and perennial allergic rhinitis or rhinocojunctivitis Urticaria.

DOSAGE AND MODE ROUTE OF ADMINISTRATION:
Posology
Allergic rhinitis/rhinocojunctivitis
For children 12 years of age and above and adults the following dosage recommendations apply: 10 mg ebastine once daily. In cases of severe symptoms the dose may be increased to 20 mg ebastine once daily.
Urticaria
For adults above 18 years of age the following dosage recommendations apply: 10 mg ebastine once daily.
Paediatric population
The safety and efficacy of Ebastine in children under the age of 12 years have not been established.
Special populations
In patients with mild, moderate or severe renal impairment or mild to moderate hepatic impairment it is not necessary to adjust dose.
There is no experience with doses over 10 mg in patients with severe hepatic impairment; therefore the dose should not exceed 10 mg in patients with severe hepatic impairment.
Treatment may be prolonged until symptoms disappear.
Method of administration
For oral administration
To be dispersed in water for oral use.

CONTRAINDICATIONS &PRECAUTION(S), WARNING(S):
Hypersensitivity to the active substance or to any of the other excipients

PRECAUTIONS & WARNINGS:
Caution should be exercised when ebastine is administered to patients with known prolongation of the QTc interval on the electrocardiogram, hypokalemia and in cases of concomitant use of medicinal products known to prolong the QTc interval or inhibit the hepatic CYP450 2J2, 4F12 or 3A4 enzyme system, such as azole antifungal agents and macrolide antibiotics.
Since there is a pharmacokinetic interaction with antimycotics of the imidazole type, like ketoconazole and itraconazole, or macrolid antibiotics, like erythromycin, and antituberculosis agents, like rifampicin care should be taken when prescribing ebastine with drugs belonging to such groups.
Ebastine should be used with caution in patients with severe hepatic impairment.

Excipients
This medicinal product contains aspartame (E951), a source of phenylalanine, and may be harmful for patients with phenylketonuria.

PREGNANCY AND LACTATION:
Pregnancy
There are limited amount of data from the use of ebastine in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of ebastine during pregnancy.
Lactation
It is not known whether the active substance is excreted in human milk. High protein binding (>97%) of ebastine and its main metabolite, carebastine, suggest no excretion of drug into breast milk. In the rat, excretion of ebastine in milk has been shown. As a precautionary measure, it is preferable to avoid the use of ebastine during lactation.
Fertility
There are no fertility data with ebastine in humans.

280 mm

PHARMACODE READING DIRECTION

Back Side

140 mm

35 mm | 35 mm | 35 mm | 35 mm | 35 mm | 35 mm | 35 mm | 35 mm

INTERACTIONS:
Pharmacokinetic interactions have been observed when ebastine is given with ketoconazole or itraconazole and erythromycin. These interactions resulted in increased plasma concentrations of ebastine and to a lesser extent of carebastine which were, nevertheless, not associated with any clinically significant Pharmacodynamic consequences.
Pharmacokinetic interactions have been observed when ebastine is given with rifampicin. These interactions could result in lower plasma concentrations and reduced antihistamine effects.
No interactions have been reported between ebastine and theophylline, warfarin, cimetidine, diazepam and alcohol.
The administration of ebastine with food does not cause a modification in its clinical effect.

ADVERSE EFFECTS:
In a pooled analysis of placebo-controlled clinical trials with 5,708 patients on ebastine, the most commonly reported adverse reactions were dry mouth and somnolence.
ADRs reported in clinical trials in children (n=460) were similar to those observed in adults.
The table below lists the adverse reactions from clinical trials and post-marketing experience.

SOCs	Very common (≥1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Very rare (<1/10,000)
Immune system disorders				Hypersensitivity reactions (such as anaphylaxis and angioedema)	
Psychiatric disorders				Nervousness, insomnia	
Nervous system disorders	Headache	Somnolence		Dizziness, hypoesthesia, dysgeusia	Dysaesthesia
Cardiac disorders				Palpitations, tachycardia	
Respiratory, thoracic and mediastinal disorders			Epistaxis, pharyngitis, rhinitis		
Gastrointestinal disorders		Dry mouth		Abdominal pain, vomiting, nausea, dyspepsia	
Hepatobiliary disorders				Hepatitis, cholestasis, liver function test abnormal (transaminases, gamma-GT, alkaline phosphatase and bilirubin increased)	
Skin and subcutaneous disorders				Urticaria, rash, dermatitis	Exanthema, eczema
Reproductive system disorders				Menstrual disorders	Dysmenorrhea
General disorders				Oedema, asthenia	

OVERDOSAGE AND TREATMENT:
Symptoms
In studies with a high dosage, no clinically significant signs or symptoms were observed up to 100 mg given once-daily. Overdose may increase the risk of sedation and antimuscarinic effects.
Treatment
There is no specific antidote for ebastine. Gastric lavage, monitoring of vital functions including ECG and symptomatic treatment should be carried out. Intensive care may be required in the event of central nervous symptoms developing.

STORAGE CONDITION:
STORE AT TEMPERATURES NOT EXCEEDING 30°C.

DOSAGE FORMS AND PACKAGING AVAILABLE:
Alu/Alu Strip Foil pack of 10's (Box of 30's)

INSTRUCTIONS AND SPECIAL PRECAUTIONS FOR HANDLING AND DISPOSAL (IF APPLICABLE):
Not Applicable

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:
Marketing Authorization Holder
Brown & Burk Philippines Inc
U-501, 5/F., SEDCCO 1 Bldg., 120 Rada cor.,
Legaspi Sts., Legaspi Village, Makati City, Philippines

NAME AND ADDRESS OF MANUFACTURER:
MICRO LABS LIMITED
92, SIPCOT, HOSUR-635 126,
TAMIL NADU, INDIA

CAUTION STATEMENT:
FOODS, DRUGS, DEVICES, AND COSMETICS ACT PROHIBITS DISPENSING WITHOUT PRESCRIPTION.

ADR REPORTING STATEMENT:
FOR SUSPECTED ADVERSE DRUG REACTION, REPORT TO THE FDA: www.fda.gov.ph
Seek medical attention immediately at the first sigh of Adverse Drug Reaction.

REGISTRATION NUMBER:
DR NO. : XY43157

DATE OF FIRST AUTHORIZATION:
5 FEB, 2014.

DATE OF REVISION OF PACKAGE INSERT:
Mar. 2018

EXG-ML01I-1506/A

280 mm

14 (L) x 8 (H) mm

PHARMACODE READING DIRECTION

385

Size : 140 (L) x 280 (H) mm
Drg. No.: W0990006084Z-000
Folding size: 35 x 140 mm
Carton size: 47 x 20 x 118 mm