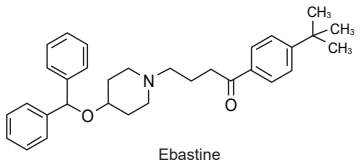
Ebaget-D™

[E b a s t i n e]

ایباگیٹ-ڈی

Orodispersible Tablets
10mg & 20mg

DESCRIPTION
Ebaget-D (Ebastine) is a piperidine derivative and is a non-sedating antihistamine with a long duration of action. It does not have significant sedative or antimuscarinic actions. Chemically, it is 1-[4-(1,1-Dimethylethyl)phenyl]-4-[4-(diphenylmethoxy)piperidin-1-yl] butan-1-one. Its molecular formula is $C_{32}H_{39}NO_2$ and the structural formula is:



Ebastine

QUALITATIVE AND QUANTITATIVE COMPOSITION
Ebaget-D (Ebastine) Orodispersible Tablets are available for oral administration as:

Ebaget-D Tablets 10mg
Each orodispersible tablet contains:
Ebastine Ph. Eur...10mg

Ebaget-D Tablets 20mg
Each orodispersible tablet contains:
Ebastine Ph. Eur...20mg

CLINICAL PHARMACOLOGY
Mechanism of Action
Ebastine and its active metabolite, carebastine, are selective antihistamines acting on peripheral H_1 receptors, which appear to have no sedative and anticholinergic side effects at the recommended doses.

Pharmacokinetics
Ebastine is rapidly absorbed after oral intake and undergoes a very important intestinal and hepatic first-pass effect. It is almost completely transformed into its pharmacologically active acid metabolite, carebastine. After a single oral dose of 10mg, the peak plasma concentration is reached after 2 to 4 hours, with levels ranging from 80 to 100 ng/ml.
The half-life of the acid metabolite is between 15 and 19 hours, with urinary excretion of 66%, mainly as a conjugated metabolite. After repeated administration of ebastine at a single dose of 10mg once daily, the steady state is reached in 3-5 days, with peak plasma concentrations ranging from 130 to 160 ng/ml. Ebastine and carebastine are strongly bound to plasma proteins, with a binding rate greater than 90%.

Special Population
In patients with renal insufficiency, the elimination half-life of the metabolite, carebastine is prolonged to 23-26 hours. In patients with hepatic insufficiency, the half-life is 27 hours.

THERAPEUTIC INDICATIONS
Ebaget-D (Ebastine) is indicated for the symptomatic treatment of:
- Seasonal and perennial allergic rhinitis / rhinoconjunctivitis
- Urticaria

DOSAGE & ADMINISTRATION
The recommended dose of Ebaget-D (Ebastine) Orodispersible Tablets are:

Allergic rhinitis / rhinoconjunctivitis
For children 12 years of age and above and adults: 10mg ebastine once daily. In cases of severe symptoms the dose may be increased to 20mg ebastine once daily.

Urticaria
For children 12 years of age and above and adults: 10mg ebastine once daily.

Special Population
There is no experience with doses greater than 10mg in patients with severe hepatic impairment. Therefore, the 10mg dose should not be exceeded in patients with severe hepatic impairment. Treatment should be continued until symptoms disappear.

Method of Administration
- Ebaget-D (Ebastine) Orodispersible Tablets should be placed on the tongue where it will disperse: no water or other fluid is required.
- Ebaget-D (Ebastine) Orodispersible Tablets can be taken at meal times or independently of meals.

ADVERSE REACTIONS
Very Common: Headache.

Common: Somnolence & dry mouth.

Uncommon: Epistaxis, pharyngitis and rhinitis.

Rare: Hypersensitivity reactions (such as anaphylaxis and angioedema), nervousness, insomnia, dysaesthesia, hypoaesthesia, dysgeusia, dizziness, tachycardia, palpitations, nausea, abdominal pain, dyspepsia, vomiting, hepatitis, cholestasis, abnormal liver function test (transaminases, gamma-GT, alkaline phosphatase and bilirubin increased), urticaria, rash, dermatitis, menstrual disorders, oedema & asthenia.

Very rare: Exanthema, eczema and dysmenorrhoea.

"To report SUSPECTED ADVERSE REACTIONS to Getz Pharma's Pharmacovigilance Section, please contact at dsafety@getzpharma.com or +92-21-38636363"

CONTRAINDICATIONS
Ebastine is contraindicated:
- In patients with known sensitivity to ebastine or to any excipient of the product.
- In children under 12 years of age in the absence of efficacy and safety data.
- In cases of phenylketonuria, due to the presence of aspartame.

PRECAUTIONS
- Ebastine should be used with caution in patients with severe hepatic impairment.
- Since there is a pharmacokinetic interaction with antimycotics of the imidazole type, like ketoconazole and itraconazole or macrolide antibiotics, like erythromycin and antituberculosis agents, like rifampicin, care should be taken when prescribing ebastine with drugs belonging to such groups.
- In sensitive patients who react unusually to ebastine, it is advisable to know the individual reactions before a patient drives or carries out complicated activities: somnolence or dizziness may occur.

Pregnancy
Ebastine should be used during pregnancy only if the potential benefit to the patient outweighs the risk to the patient and fetus.

Nursing Mothers
It is unknown if the drug is excreted in human milk. Because many drugs are excreted in human milk precaution should be exercised, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

DRUG INTERACTION
- Pharmacokinetic interactions were observed when ebastine was given with ketoconazole or itraconazole and erythromycin. These interactions lead to an increase in plasma concentrations of ebastine and, to a lesser extent, carebastine, which were nonetheless not associated with a significant clinical consequence. However, as a precaution, the combination with ketoconazole, itraconazole, erythromycin, clarithromycin, josamycin should be avoided: increased risk of developing ventricular arrhythmias in predisposed subjects

(long QT syndrome, congenital).

- Pharmacokinetic interactions were observed when ebastine was given with rifampicin. These interactions may lead to lower plasma concentrations of ebastine and reduce the antihistamine effect.

OVERDOSAGE

Symptoms

In studies with a high dosage, no clinically significant signs or symptoms were observed up to 100mg 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

Do not store above 30°C.
Protect from light and moisture.

The expiration date refers to the product correctly stored at the required conditions.

HOW SUPPLIED

Ebaget-D (Ebastine) Orodispersible Tablets 10mg are available in blister pack of 10's.
Ebaget-D (Ebastine) Orodispersible Tablets 20mg are available in blister pack of 10's.

Keep out of reach of children.

To be sold on prescription of a registered medical practitioner only.

Please read the contents carefully before use.
This package insert is continually updated from time to time.

Manufactured by:

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29-30/27,
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