

# Kestine™

(Ebastine)



## COMPOSITION

### Kestine 10mg Tablet:

Each film-coated tablet contains: Ebastine 10mg

### Kestine 20mg Tablet:

Each film-coated tablet contains: Ebastine 20mg

### Kestine Liquid:

Each 5mL contains: Ebastine 5mg

## DESCRIPTION

Ebastine a piperidine derivative, is a non-sedating antihistamine, with a long duration of action. It does not have significant sedatives or antimuscarinic actions.

## INDICATIONS

It is indicated in the symptomatic treatment of;

- allergic rhinitis (seasonal and perennial) associated or not with allergic conjunctivitis
- Idiopathic chronic urticaria
- allergic dermatitis

## DOSAGE AND ADMINISTRATION

**Allergic rhinitis:** The recommended dose is 10mg Kestine (ebastine) once daily. In the event of severe symptoms, the dose may be increased to 20mg once daily. This can be taken as two doses of 10mg or as one dose of 20mg.

**Urticaria:** The adult dose is 10mg of oral Kestine (ebastine) daily.

**Allergic dermatitis:** The adult dose is 10mg of oral Kestine (ebastine) daily.

### The dosage of Kestine (Ebastine) Oral Liquid is as:

**Adults and children over 12 years of age:** The recommended dose is 10ml (10mg) (2 doses of 5ml) once daily.

**Children aged 6 to 11 years:** One dose of 5ml (5mg of ebastine) once a day.

**Children aged 2 to 5 years:** The usual dose is 2.5ml (2.5 mg of ebastine) once a day.

**Children under 2 years of age:** The safety of ebastine has not been established for children under 2 years of age.

### In Special groups

**Elderly patients:** It is not necessary to adjust the dose.

**Renal insufficiency:** It is not necessary to adjust the dose.

**Hepatic insufficiency:** It is not necessary to adjust the dose in patients with mild or moderate liver impairment. There is no experience with doses over 10mg in patients with severe hepatic insufficiency; therefore the dose of 10mg ebastine per day should not be exceeded in these patients.

## CONTRAINDICATIONS

Hypersensitivity to the active ingredient or to any excipient.

## WARNINGS AND PRECAUTIONS

- Caution should be taken when prescribing ebastine in combination with azole antimycotic agents, type ketoconazole and itraconazole, or macrolide antibiotics type erythromycin.
- Caution should be taken when ebastine prescribing with drugs belonging to antituberculous type rifampicin.
- Ebastine should be used with caution in patients with severe hepatic insufficiency.
- Ebastine at recommended therapeutic doses does not affect the ability to drive or operate machines. However, in sensitive subjects 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.
- This medicine contains lactose. Patients with hereditary galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.
- This medicinal product contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medication.
- This medicinal product may cause stomach upset and diarrhea because it contains glycerol-polyethylene glycol oxytate.

## DRUG 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.

- 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.

## EXCIPIENTS FOR KESTINE LIQUID

Glycerin, Lactic Acid, Sorbitol, Methyl Paraben Sodium, Propyl Paraben Sodium, Neohesperidine Dihydrochalcone, Polyoxyl 40 Hydrogenated Castor Oil, Sodium Hydroxide, Anethole, Simethicone Emulsion.

## EXCIPIENTS FOR KESTINE TABLET

Microcrystalline Cellulose, Lactose, Croscarmellose Sodium, Pregelatinized Starch, Magnesium Stearate, Hydroxypropyl Methylcellulose, Polyethylene glycol (6000), Titanium Dioxide (in Kestine 20mg only).

## PREGNANCY

There are limited amount of data from the use of ebastine in pregnant women. As a precautionary measure, it is preferable to avoid the use of ebastine during pregnancy.

## LACTATION

It is not known whether ebastine is excreted in human milk. As a precautionary measure, it is preferable to avoid the use of ebastine during lactation.

## ADVERSE EFFECTS

The commonly reported undesirable effects were headache, somnolence, dry mouth, hypersensitivity reactions (such as anaphylaxis and angioedema), nervousness, insomnia, dizziness, hypoesthesia, dysgeusia, palpitations, tachycardia, abdominal pain, nausea, vomiting, dyspepsia, hepatitis, cholestasis, liver function test abnormal (transaminases, gamma GT, alkaline phosphatase and bilirubin increased), urticaria, rash, dermatitis, menstrual disorder, oedema, asthenia, increased appetite and weight increased.

## OVERDOSAGE

There is no specific antidote for ebastine. Gastric lavage, monitoring of vital functions including ECG and symptomatic treatment should be carried out.

## DOSAGE AND INSTRUCTIONS

To be sold and used on the prescription of a registered medical practitioner only. Keep out of reach of children. Do not store above 30°C. Keep in a dry place. Protect from light.

## PRESENTATION

### Kestine 10mg Tablets:

Alu. PVC. Blister Pack of 2 x 7's.

### Kestine 20mg Tablets:

Alu. PVC. Blister Pack of 2 x 7's.

### Kestine Liquid:

Glass Bottle of 30mL with graduated spoon.

کیسٹین  
ایبستین

خوراک و ہدایات:

صرف مستند ڈاکٹر کے نسخے کے مطابق ہی دوا فروخت اور استعمال کی جائے۔

بچوں کی پہنچ سے دور رکھیں۔ 30°C سے زیادہ درجہ حرارت پر نہ رکھیں۔

خشک جگہ پر رکھیں۔ روشنی سے بچائیں۔

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