

# KESTINE® film-coated tablets

Ebastine (10mg, 20mg)

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## What *Kestine* is used for

*Kestine* is indicated for the symptomatic treatment of allergic conditions such as seasonal and perennial allergic rhinitis with or without allergic conjunctivitis (runny nose, itchy nose or eyes, watery eyes, sneezing, etc.), and chronic urticaria (*Kestine* 10mg only).

## How *Kestine* works

*Kestine* belongs to a group of drugs known as antihistamines (antiallergics).

## Before you use *Kestine*

### - When you must not use it

If you are allergic to ebastine or any of the other ingredients of this medicine (included in section Product Description).

If you or your child is under 12 years of age.

### Pregnancy and lactation

If you are pregnant or breast-feeding, think you might be pregnant or plan to become pregnant, consult your doctor or pharmacist before using this medicine.

### Pregnancy

Due to insufficient data to ensure the perfect safety of this drug when administered during pregnancy, its use is not recommended in pregnant women.

### Breast-feeding

It is not known whether the drug passes into human milk, and therefore it is not recommended for women who are breast-feeding.

### - Before you start to use it

Ask your doctor or pharmacist for advice before taking *Kestine*.

This medicine should be used with precaution:

- If you have a history of heart disease, cardiac discomfort or palpitations, tell your doctor.
- if you suffer from severe liver disease, tell your doctor (see "How to use *Kestine*").
- *Kestine* can cause dry mouth. At long term treatment it is therefore important to have a good mouth hygiene to prevent risk for caries (the teeth should be cleaned with fluoride containing tooth paste twice daily).

Do not use this medicine if you have a severe acute allergic reaction, as ebastine (the active substance in this medicine) takes from 1 to 3 hours to be effective.

### - Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines

- The combination of this drug with medications based on ketoconazole, itraconazole, erythromycin, clarithromycin, and josamycin is generally discouraged.
- Simultaneous administration of this drug with rifampicin (an active substance to treat tuberculosis) may result in decreased ebastine levels in the blood and reduced antihistamine effects.

No interactions have been reported between ebastine and theophylline, warfarin, cimetidine, diazepam and alcohol.

## How to use *Kestine*

### - Taking *Kestine* with food and drink

The tablets can be taken with or without food.

### - How much to use

## Use in adults and children over the age of 12:

Allergic Rhinitis: The usual dose is 10 mg of ebastine once daily. In the event of severe symptoms, the dose may be increased to 20 mg once daily.  
Chronic Urticaria: The usual dose is 10 mg of ebastine once daily.

## Use in patients with severe liver

**disease:** Do not exceed the dose of 10 mg of ebastine a day.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Remember to take your medicine.

### - When to use it

Use as directed by your doctor or pharmacist.

### - How long to use it

Continue using *Kestine* for as long as your doctor recommends.

Your doctor will indicate the duration of your treatment with *Kestine*.

### - If you forget to use it

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicinal product, ask your doctor or pharmacist.

### - If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

## While you are using it

### - Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Kestine*.

Tell your doctor immediately if you become pregnant while taking this medication.

### - Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

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Do not give *Kestine* to anyone else, even if they have the same symptoms or condition as you.

## - Things to be careful of

### Driving and using machines

In humans, no effects have been observed on psychomotor function or the ability to drive or use machines at the recommended therapeutic doses. However, it is recommended to know individual reactions before driving or performing activities requiring special attention: risk of drowsiness or dizziness.

### Kestine contains lactose

This medicine contains lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## Side effects

Like all medicines, *Kestine* can cause side effects, although not everybody gets them.

In clinical trials and post-marketing experience, the following side effects have been observed:

Very common (may affect more than 1 in 10 people):

- Headache

Common (may affect up to 1 in 10 people):

- Drowsiness
- Dry mouth

Rare (may affect up to 1 in 1000 people):

- Hypersensitivity reactions: allergic reactions (such as anaphylaxis and Quincke's oedema)
- Nervousness, sleeplessness
- Dizziness, decreased feeling of touch or sensation, taste change
- Palpitations, abnormal heart rhythm
- Stomach pain, vomiting, nausea, digestive problems
- Liver problems, abnormal liver function tests (transaminases, gamma-GT, alkaline phosphatase and bilirubin increased)
- Urticaria, rash, skin inflammation
- Menstrual disorders
- Oedema (fluid retention), fatigue

Very rare (may affect up to 1 in 10,000 people)

- Severe allergic manifestation

Unknown:

- Increased appetite
- Weight Increased

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website [nptra.gov.my](http://nptra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

## Storage and Disposal of *Kestine*

### - Storage

Keep out of the reach and sight of children.

Store below 30°C.

### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## Product Description

### - What it looks like

*Kestine* comes in the form of film-coated tablets for oral administration packaged in PVC/Aluminium blisters. The tablets are white, round and have "E/10" marked for *Kestine* 10 mg and "E20" for *Kestine* 20 mg on one side.

### - Ingredients

#### - Active ingredient(s)

The active substance is ebastine.

Each tablet of *Kestine* 10 mg

contains 10 mg of ebastine.

Each tablet *Kestine* 20 mg contains 20 mg of ebastine.

#### - Inactive ingredients

The other ingredients (excipients) are: *Tablet core*: microcrystalline cellulose, pregelatinised maize starch, lactose monohydrate, croscarmellose sodium and magnesium stearate.

*Coating*: hypromellose, macrogol 6000 and titanium dioxide.

### - MAL number(s):

*Kestine* 10mg: MAL19096029AZ

*Kestine* 20mg: MAL19096026AZ

## Manufacturer

INDUSTRIAS FARMACÉUTICAS ALMIRALL, S.A.

Ctra. de Martorell, 41-61

08740 Sant Andreu de la Barca

(Barcelona) SPAIN

## Product Registration Holder

EURODRUG LABORATORIES (M) SDN BHD

T2-21-10, The Square, One City,

Jalan USJ 25/1C,

47650 Subang Jaya,

Selangor, Malaysia

## Date of Revision

10/04/2026

## Serial Number

NPRA (R1/1) 13062024/115