LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Ebateva
(ebastine)

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Ebateva

(ebastine)

Orodispersible tablet, 10mg and 20mg

This is a summary of the public assessment report (PAR) for Ebateva. It explains how Ebateva was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Ebateva.

For practical information about using Ebateva, patients should read the package leaflet or contact their doctor or pharmacist.

What is Ebateva and what is it used for?

Ebateva is a ‘generic medicine’. This means that Ebateva is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Kestine.

In adults and children aged 12 years and older Ebateva is used to alleviate the symptoms of seasonal rhinitis (hay fever) and perennial allergic rhinitis, including cases with allergic conjunctivitis.

In adults over the age of 18 years Ebateva 10 mg is also used to alleviate itching and the development of wheals in urticaria (nettle rash).

How does Ebateva work?

Ebastine is an antihistamine that helps relieve allergy symptoms such as sneezing, runny nose, watery eyes and itchy skin rashes.

How is Ebateva used?

The pharmaceutical form of Ebateva is orodispersible tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Ebateva have been shown in studies?

Because Ebateva is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Kestine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Ebateva?

Because Ebateva is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Ebateva approved?

It was concluded that, in accordance with EU requirements, Ebateva has been shown to have comparable quality and to be bioequivalent to the reference medicine Kestine. Therefore, the Medical Products Agency in Sweden decided that, as for Kestine, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Ebateva?

A risk management plan has been developed to ensure that Ebateva is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Ebateva, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Ebateva

The marketing authorisation for Ebateva was granted on 2014-02-06 in Sweden.

The full PAR for Ebateva can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Ebateva, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2014-02.