LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Bilastin Teva

(bilastine)

SE/H/2034/01/DC

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bilastine

Tablet, 20 mg

This is a summary of the public assessment report (PAR) for Bilastin Teva. It explains how Bilastin Teva 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 Bilastin Teva.

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

What is Bilastin Teva and what is it used for?

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

Bilastin Teva is used to relieve the symptoms of hay fever (sneezing, itchy, runny, blocked-up nose and red and watery eyes) and other forms of allergic rhinitis. It may also be used to treat itchy skin rashes (hives or urticaria).

How does Bilastin Teva work?

Bilastin Teva contains the active substance bilastine which is an antihistamine. It works as an antagonist for the histamine receptor, which means it binds to, but does not activate the histamine receptors.

How is Bilastin Teva used?

The pharmaceutical form of Bilastin Teva is 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 in Sweden.

What benefits of Bilastin Teva have been shown in studies?

Because Bilastin Teva is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Bilaxten.

What are the possible side effects of Bilastin Teva?

Because Bilastin Teva is a generic 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 Bilastin Teva approved?

It was concluded that, in accordance with EU requirements, Bilastin Teva has been shown to have comparable quality and to be bioequivalent to the reference medicine Bilaxten. Therefore, the Medical Products Agency in Sweden decided that, as for Bilaxten, 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 Bilastin Teva?

A risk management plan has been developed to ensure that Bilastin Teva 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 Bilastin Teva, 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 Bilastin Teva

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

This summary was last updated in 2021-05.