LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Bilastine Tiefenbacher

(bilastine)

SE/H/2036/01/DC

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Summary Public Assessment Report

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bilastine

Tablet, 20 mg

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

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

What is Bilastine Tiefenbacher and what is it used for?

Bilastine Tiefenbacher is a 'generic medicine'. This means that Bilastine Tiefenbacher is similar to a 'reference medicine' already authorised in the European Union (EU) called Bilaxten.

Bilastine Tiefenbacher 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 Bilastine Tiefenbacher work?

Bilastine Tiefenbacher 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 Bilastine Tiefenbacher used?

The pharmaceutical form of Bilastine Tiefenbacher 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 Bilastine Tiefenbacher have been shown in studies?

Because Bilastine Tiefenbacher 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 Bilastine Tiefenbacher?

Because Bilastine Tiefenbacher 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 Bilastine Tiefenbacher approved?

It was concluded that, in accordance with EU requirements, Bilastine Tiefenbacher 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 Bilastine Tiefenbacher?

A risk management plan has been developed to ensure that Bilastine Tiefenbacher 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 Bilastine Tiefenbacher, 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 Bilastine Tiefenbacher

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

This summary was last updated in 2021-05.