LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Bilata
bilastine

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Bilata
bilastine

Tablet, 20 mg

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

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

What is Bilata and what is it used for?
Bilata is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Bilaxten.

Bilata is used to relieve the symptoms of hayfever (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 Bilata work?

Bilata contains the active substance bilastine which is an antihistamine. It works by blocking the receptors to which histamine, a substance in the body that causes allergic symptoms, normally attaches itself. When the receptors are blocked, histamine cannot have its effect, and this leads to a decrease in the symptoms of allergy.

How is Bilata used?

The pharmaceutical form of Bilata 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 Bilata have been shown in studies?

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

Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Bilata?

Because Bilata 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 side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Bilata approved?

It was concluded that, in accordance with EU requirements, Bilata has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Bilaxten. Therefore, the Swedish Medical Products Agency 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 Bilata?

A risk management plan has been developed to ensure that Bilata 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 Bilata, 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 Bilata

The full PAR for Bilata can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Bilata

This summary was last updated in 2022-03.