LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Bilacina
(bilastine)

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Summary Public Assessment Report

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bilastine

Orodispersible tablet, 10 mg, 20 mg

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

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

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

The product is used in the treatment of symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria.

Bilacina, 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).

Bilacina 10 mg tablets are indicated in children from 6 years of age with a body weight of at least 20 kg and also indicated in adults and adolescents.

Bilacina 20 mg tablets are indicated in in adults and adolescents.

How does Bilacina work?

Bilacina is a antihistamine, inhibited histamine-induced wheal and flare skin reactions for 24 hours following single doses.

How is Bilacina used?

The pharmaceutical form 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 in Sweden.

What benefits of Bilacina have been shown in studies?

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

What are the possible side effects from Bilacina?

Because the product 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 Bilacina approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for the reference medicine, 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 Bilacina?
A risk management plan has been developed to ensure that the product 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, 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 Bilacina

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

This summary was last updated in 2022-11.