LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Macitentan Bioglan (macitentan)

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Summary Public Assessment Report

Macitentan Bioglan
macitentan

Film-coated tablet, 10 mg

This is a summary of the public assessment report (PAR) for Macitentan Bioglan. 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 Macitentan Bioglan 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 Opsumit.

Macitentan Bioglan contains the active substance macitentan, which belongs to the class of medicines called "endothelin receptor antagonists".

Macitentan Bioglan is used for the long-term treatment of pulmonary arterial hypertension (PAH):
- in adults of WHO Functional Class (FC) II to III
- in children under 18 years and body weight of at least 40 kg with WHO Functional Class (FC) II to III.

It can be used on its own or with other medicines for PAH. PAH is high blood pressure in the blood vessels that carry blood from the heart to the lungs (the pulmonary arteries). In people with PAH, these arteries get narrower, so the heart has to work harder to pump blood through them. This causes people to feel tired, dizzy, and short of breath.

How does Macitentan Bioglan work?

Macitentan Bioglan widens the pulmonary arteries, making it easier for the heart to pump blood through them. This lowers the blood pressure, relieves the symptoms and improves the course of the disease.

How is Macitentan Bioglan used?
The pharmaceutical form is film-coated 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 Macitentan Bioglan have been shown in studies?

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

What are the possible side effects from Macitentan Bioglan?

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 Macitentan Bioglan approved?

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

The product has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below “What measures are being taken to ensure the safe and effective use of Macitentan Bioglan?”

What measures are being taken to ensure the safe and effective use of Macitentan Bioglan?
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.

All patients who are expected to use Macitentan Bioglan should be provided with a patient card describing potential risks that can occur during treatment. For more details, please see the full PAR for Macitentan Bioglan on the following website: MRI - Home.

Other information about Macitentan Bioglan
The full PAR for Macitentan Bioglan can be found on the following website: MRI - Home. For more information about treatment with Macitentan Bioglan, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-01.