

Summary Public Assessment Report

Bisoprolol Medical Valley (bisoprolol fumarate)

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(bisoprolol fumarate)

Tablet, 1.25 mg, 2.5 mg, 3.75 mg, 5 mg, 7.5 mg, 10 mg

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

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

What is Bisoprolol Medical Valley and what is it used for?

Bisoprolol Medical Valley is a ‘generic medicine’. This means that Bisoprolol Medical Valley is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Cardicor.

The active substance in Bisoprolol Medical Valley is bisoprolol. Bisoprolol belongs to a group of medicines called beta-blockers. These medicines work by affecting the body’s response to some nerve impulses, especially in the heart. As a result, bisoprolol slows down the heart rate and makes the heart more efficient at pumping blood around the body.

How does Bisoprolol Medical Valley work?

Heart failure occurs when the heart muscle is weak and unable to pump enough blood to supply the body's needs. Bisoprolol Medical Valley is used in combination with other medicines suitable for this condition (such as ACE-inhibitors, diuretics, and heart glycosides) to treat stable chronic heart failure.

How is Bisoprolol Medical Valley used?

The pharmaceutical form of Bisoprolol Medical Valley is tablets 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.

What benefits of Bisoprolol Medical Valley have been shown in studies?

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

What are the possible side effects of Bisoprolol Medical Valley?

Because Bisoprolol Medical Valley is a generic medicine and is bioequivalent to the reference 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 Bisoprolol Medical Valley approved?

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

A risk management plan has been developed to ensure that Bisoprolol Medical Valley 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 Bisoprolol Medical Valley, 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 Bisoprolol Medical Valley

The marketing authorisation for Bisoprolol Medical Valley was granted on 2019-01-23 in Sweden.

The full PAR for Bisoprolol Medical Valley can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Bisoprolol Medical Valley, please read the package leaflet for [1.25 mg](#), [2.5 mg](#), [3.75 mg](#), [5 mg](#), [7.5 mg](#), [10 mg](#) or contact your doctor or pharmacist.

This summary was last updated in 2019-03.