LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Isomex
(isosorbide mononitrate)

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Isomex
isosorbide mononitrate

Prolonged-release tablet, 30 mg

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

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

What is Isomex and what is it used for?

Isomex is a ‘generic medicine’. This means that Isomex is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Imdur.

Isomex is used as preventive treatment of angina pectoris in adults.

How does Isomex work?

Isomex contains the active ingredient isosorbide mononitrate, which belongs to a group of medicines called nitrates. This type of medicine works by widening blood vessels and thereby facilitates the heart's work for those with angina pectoris.

How is Isomex used?

The pharmaceutical form of Isomex is prolonged-release 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.

What benefits of Isomex have been shown in studies?

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

What are the possible side effects of Isomex?

Because Isomex 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 Isomex approved?

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

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

The marketing authorisation for Isomex was granted on 2017-02-24 in Sweden.

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

This summary was last updated in 2017-03.