

Summary Public Assessment Report

Furosemid Medical Valley (furosemide)

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(furosemide)

Tablet, 20 mg, 40 mg

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

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

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

Furosemid Medical Valley is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Lasix for the 40 mg strength and Lasilix Faible for the 20 mg strength respectively.

Furosemid Medical Valley is used to treat high blood pressure as well as swelling in the lung caused by excess fluid. It is also used to treat swelling caused by excess fluid in the tissues, occurring in patients with

- heart disease
- liver disease
- kidney disease. This also includes a kidney disease with massive protein loss, increased fat levels and swelling through fluid accumulation called nephrotic syndrome. If you have this particular kidney disease, treatment of the underlying disorder has priority.

How does Furosemid Medical Valley work?

Furosemid Medical Valley is a diuretic, which is a medicine that increases urine output. This increases the amount of fluid that is excreted from the body and gives an antihypertensive effect.

How is Furosemid Medical Valley used?

The pharmaceutical form of Furosemid Medical Valley 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 Furosemid Medical Valley have been shown in studies?

Because Furosemid Medical Valley is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Lasix for 40 mg and Lasilix Faible for 20 mg respectively.

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

What are the possible side effects from Furosemid Medical Valley?

Because Furosemid Medical Valley 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 Furosemid Medical Valley approved?

It was concluded that, in accordance with EU requirements, Furosemid Medical Valley has been shown to have comparable quality and is considered to be bioequivalent to the reference medicines Lasix for 40 mg and Lasilix Faible for 20 mg respectively. Therefore, the Swedish Medical Products Agency decided that, as for Lasix and Lasilix Faible, 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 Furosemid Medical Valley?

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

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

This summary was last updated in 2021-12.