LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Labetalol S.A.L.F.
(labetalol hydrochloride)

SE/H/1568/01/DC

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Summary Public Assessment Report

Labetalol S.A.L.F.

(labetalol hydrochloride)

Solution for injection/ infusion 5 mg/ml

This is a summary of the public assessment report (PAR) for Labetalol S.A.L.F. It explains how Labetalol S.A.L.F. 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 Labetalol S.A.L.F.

For practical information about using Labetalol S.A.L.F., patients should read the package leaflet or contact their doctor or pharmacist.

What is Labetalol S.A.L.F. and what is it used for?

Labetalol S.A.L.F. is a 'generic medicine'. This means that Labetalol S.A.L.F. is similar to a 'reference medicine' already authorised in the European Union (EU) called Trandate.

Labetalol S.A.L.F is used to treat severe hypertension (high blood pressure), including severe hypertension of pregnancy (pregnancy-induced high blood pressure) when rapid control of blood pressure is necessary. Labetalol S.A.L.F. may also be used to control blood pressure during anaesthesia.

How does Labetalol S.A.L.F. work?

Labetalol S.A.L.F. contains the active substance labetalol. Labetalol belongs to a group of medicines called alpha and beta-blocking agents. These medicines lower blood pressure by blocking the receptors in the cardiovascular (circulatory) system, causing a decrease in blood pressure in the blood vessels far from the heart.

How is Labetalol S.A.L.F. used?

The pharmaceutical form of Labetalol S.A.L.F. is solution for injection/ infusion.

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 Labetalol S.A.L.F. have been shown in studies?

No additional studies were needed as Labetalol S.A.L.F. is a generic medicine that is given by infusion/intravenous injection and contains the same active substance as the reference medicine, Trandate.

What are the possible side effects of Labetalol S.A.L.F.?

Because Labetalol S.A.L.F. 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 restrictions, see the package leaflet.

Why is Labetalol S.A.L.F. approved?

It was concluded that, in accordance with EU requirements, Labetalol S.A.L.F. has been shown to have comparable quality and to be similar to the reference medicine Trandate. Therefore, the Medical Products Agency in Sweden decided that, as for Trandate, 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 Labetalol S.A.L.F.?

A risk management plan has been developed to ensure that Labetalol S.A.L.F. 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 Labetalol S.A.L.F., 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 Labetalol S.A.L.F.

The marketing authorisation for Labetalol S.A.L.F. was granted on 2016-12-19 in Sweden.

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

This summary was last updated in 2016-12.