LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Fenylefrin Aguettant (phenylephrine hydrochloride)

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Summary Public Assessment Report

Fenylefrin Aguettant
phenylephrine hydrochloride

Solution for injection/infusion, 100 microgram/ml

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

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

What is Fenylefrin Aguettant and what is it used for?

Fenylefrin Aguettant is a medicine with 'well-established use'. This means that the medicinal use of the active substance of Fenylefrin Aguettant is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Fenylefrin Aguettant is used in the treatment of low blood pressure that can occur during different types of anesthesia.

How does Fenylefrin Aguettant work?

Fenylefrin Unimedic belongs to a group called adrenergic or dopaminergic agents.

How is Fenylefrin Aguettant used?

The pharmaceutical form of Fenylefrin Aguettant 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 in Sweden.

What benefits of Fenylefrin Aguettant have been shown in studies?

As phenylephrine is a well-known substance, and its use in the treatment of hypotension during spinal, epidural or general anaesthesia is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of phenylephrine in the treatment of hypotension during spinal, epidural or general anaesthesia.

What are the possible side effects of Fenylefrin Aguettant?

For the full list of all side effects reported with Fenylefrin Aguettant, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Fenylefrin Aguettant approved?

The use of Fenylefrin Aguettant in the treatment of hypotension during spinal, epidural or general anaesthesia is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Fenylefrin Aguettant's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Fenylefrin Aguettant?

A risk management plan has been developed to ensure that Fenylefrin Aguettant 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 Fenylefrin Aguettant, 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 Fenylefrin Aguettant

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

This summary was last updated in YYYY-MM.