LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Fenylefrin Unimedic
(phenylephrine hydrochloride)

SE/H/1551/03/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Fenylefrin Unimedic
(phenylephrine hydrochloride)

Concentrate for solution for injection/infusion, 10 mg/ml

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

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

What is Fenylefrin Unimedic and what is it used for?

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

Fenylefrin Unimedic is used to treat low blood pressure that can occur during different types of anesthesia.

How does Fenylefrin Unimedic work?

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

How is Fenylefrin Unimedic used?

The pharmaceutical form of Fenylefrin Unimedic is concentrate for 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 Fenylefrin Unimedic have been shown in studies?

As phenylephrine hydrochloride is a well-known substance, and its use to treat low blood pressure that can occur during different types of anesthesia, is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of phenylephrine hydrochloride to treat low blood pressure that can occur during different types of anesthesia.

What are the possible side effects of Fenylefrin Unimedic?

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

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

Why is Fenylefrin Unimedic approved?

The use of Fenylefrin Unimedic to treat low blood pressure that can occur during different types of anesthesia 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 Unimedic'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 Unimedic?

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

The marketing authorisation for Fenylefrin Unimedic was granted on 2017-09-28 in Sweden.

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

This summary was last updated in 2017-10.