LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Fenylefrin Stragen
(phenylephrine hydrochloride)

SE/H/1415/01/DC

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Summary Public Assessment Report

Fenylefrin Stragen
(phenylephrine hydrochloride)

Solution for injection in pre-filled syringe, 50 micrograms/ml

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

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

What is Fenylefrin Stragen and what is it used for?

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

Fenylefrin Stragen is used to treat low blood pressure during anaesthesia.

How does Fenylefrin Stragen work?

This medicine belongs to a group of adrenergic and dopaminergic agents.

How is Fenylefrin Stragen used?

The pharmaceutical form of Fenylefrin Stragen is solution for injection in pre-filled syringe.

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 Stragen have been shown in studies?

As phenylephrine hydrochloride is a well-known substance, and its use in the treatment of low blood pressure during anaesthesia is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of phenylephrine hydrochloride in the treatment of low blood pressure during anaesthesia.

What are the possible side effects of Fenylefrin Stragen?

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

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

Why is Fenylefrin Stragen approved?

The use of Fenylefrin Stragen in the treatment of low blood pressure during 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 Stragen'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 Stragen?

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

The marketing authorisation for Fenylefrin Stragen was granted on 2015-10-29 in Sweden.

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

This summary was last updated in 2015-12.