

Summary Public Assessment Report

Efedrin Unimedic (ephedrine hydrochloride)

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(ephedrine hydrochloride)

solution for injection 5 mg/ml

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

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

What is Efedrin Unimedic and what is it used for?

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

Efedrin Unimedic is used in the treatment of hypotension that can occur during different types of anaesthesia. The product may only be used by or under the supervision of an anaesthesiologist.

How does Efedrin Unimedic work?

Efedrin Unimedic is used to treat hypotension that can occur during different types of anaesthesia. The product may only be used by or under the supervision of an anaesthesiologist.

Ephedrine is a sympathomimetic* amine with a direct effect on alpha- and beta receptors and an indirect effect by increasing the release of norepinephrine in the sympathetic nerve endings. Like all sympathomimetic* agents ephedrine stimulates the central nervous system, the cardiovascular system, the respiratory system and the sphincters (circular muscles) of the gastrointestinal and urinary systems.

*that mimics the effects of the sympathetic nervous system stimulation

How is Efedrin Unimedic used?

The pharmaceutical form of Efedrin Unimedic is solution for injection.

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 Efedrin Unimedic have been shown in studies?

As ephedrine hydrochloride is a well-known substance, and its use in the treatment of hypotension associated with 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 ephedrine hydrochloride in the treatment of hypotension associated with spinal, epidural, or general anaesthesia.

What are the possible side effects of Efedrin Unimedic?

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

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

Why is Efedrin Unimedic approved?

The use of Efedrin Unimedic in the treatment of hypotension associated with 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 Efedrin 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 Efedrin Unimedic?

A risk management plan has been developed to ensure that Efedrin 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 Efedrin 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 Efedrin Unimedic

The marketing authorisation for Efedrin Unimedic was granted on 2018-05-29 in Sweden.

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

This summary was last updated in 2018-06.