

Summary Public Assessment Report

Addaven

(chromic chloride hexahydrate, copper chloride dihydrate, ferric chloride hexahydrate, manganese chloride tetrahydrate, potassium iodide, sodium fluoride, sodium molybdate dihydrate, sodium selenite anhydrous, zinc chloride)

SE/H/1449/01/MR

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concentrate for solution for infusion

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

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

What is Addaven and what is it used for?

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

Addaven is used to meet basal to moderately increased requirements of trace elements in intravenous nutrition.

How does Addaven work?

Addaven is a medicine that contains trace elements. Trace elements are tiny amounts of chemicals that your body needs to function normally. Addaven is given intravenously (as a drip into a vein) when you can not eat normally. This medicine is usually used as part of a balanced intravenous diet, together with proteins, fat, carbohydrates, salts and vitamins.

How is Addaven used?

The pharmaceutical form of Addaven is concentrate for solution for infusion. Addaven shall be given as an intravenous infusion, diluted in a parenteral nutrition solution/emulsion.

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 Addaven have been shown in studies?

As the trace elements solution of Addaven; zinc, copper, iron, selenium, manganese, molybdenum, chromium, fluoride, and iodide, are a well-known substances, and its use are well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of using Addaven to meet basal to moderately increased requirements of trace elements in intravenous nutrition.

What are the possible side effects of Addaven?

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

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

Why is Addaven approved?

The use of Addaven to meet basal to moderately increased requirements of trace elements in intravenous nutrition 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 Addavens'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 Addaven?

A risk management plan has been developed to ensure that Addaven 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 Addaven, 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 Addaven

The marketing authorisation for Addaven was granted on 2014-01-16 in Sweden.

The full PAR for Addaven can be found on the following website:

<http://mri.medagencies.org/Human/>. For more information about treatment with Addaven, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2015-04.