LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Icalziss
(calcium chloride dihydrate)

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calcium chloride dihydrate

Solution for infusion, 340 mmol/l

This is a summary of the public assessment report (PAR) for Icalziss. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Icalziss and what is it used for?
The product is a medicine with 'well-established use'. This means that the medicinal use of the active substance of the product is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Icalziss is a solution for infusion containing calcium chloride dihydrate. It is used for calcium replacement during continuous renal replacement therapies (CRRT) and therapeutic plasma exchange (TPE), either as single treatment or in combination, in adults and children of all ages (above 8kg). Icalziss allows to keep calcium levels in the blood in the desired range when citrate anticoagulation treatment is used.

How does Icalziss work?
As the fifth most abundant element in the body, calcium is, among other things, essential for the functional integrity of the nervous and muscular systems and for normal cardiac contractility. Calcium also plays a prominent role in the chemical reactions involved with blood coagulation.

How is Icalziss used?
The pharmaceutical form is solution for infusion for intravenous use.

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 Icalziss have been shown in studies?
As calcium chloride dihydrate is a well-known substance, and its use in calcium replacement during extracorporeal therapies with Regional Citrate Anticoagulation (RCA) provided during Continuous Renal Replacement Therapy (CRRT) and Therapeutic Plasma Exchange (TPE), either as single treatment or in combination is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of calcium chloride dihydrate in the treatment of the above-mentioned indication.

What are the possible side effects from Icalziss?
For the full list of side effects, see section 4 of the package leaflet.
For the full list of restrictions, see the package leaflet.

Why is Icalziss approved?
The Swedish Medical Products Agency decided that the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Icalziss?
A risk management plan has been developed to ensure that the product 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, 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 Icalziss
The full PAR for Icalziss can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Icalziss, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2024-03.