LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Peditrace Novum (potassium iodide, sodium selenite anhydrous, cupric chloride dihydrate, manganese chloride tetrahydrate, zinc chloride)

SE/H/2192/01/DC

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Concentrate for solution for infusion

This is a summary of the public assessment report (PAR) for Peditrace Novum. 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 Peditrace Novum 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.

The product is used to meet the basic requirements of trace elements for preterm and term neonates, infants, children, and adolescents who cannot eat or absorb enough food through tube feeding and thus need food infused through their vein (called intravenous nutrition or parenteral nutrition). The product is added to parenteral nutrition containing all the nutrients the body needs.

How does Peditrace Novum work?
The product contains five trace elements (zinc, copper, manganese, selenium, and iodine) in very small amounts which are normally absorbed from food. These trace elements are necessary for a normal body function.

How is Peditrace Novum used?
The pharmaceutical form is concentrate for solution for infusion for intravenous 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 in Sweden.

What benefits of Peditrace Novum have been shown in studies?
As the active substances, *potassium iodide, sodium selenite anhydrous, cupric chloride dihydrate, manganese chloride tetrahydrate and zinc chloride* are well-known substances, and their use in parenteral nutrition is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of the active substances in the treatment of the above-mentioned indication.

What are the possible side effects from Peditrace Novum?
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 Peditrace Novum 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 Peditrace Novum?
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 Peditrace Novum
The full PAR for Peditrace Novum can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Peditrace Novum , please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2024-01-22.