

Summary Public Assessment Report

Natriumklorid Evolan (sodium chloride)

SE/H/2146/01/MR

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sodium chloride

Capsule, hard, 500 mg

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

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

What is Natriumklorid Evolan and what is it used for?

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

Natriumklorid Evolan is used to treat sodium deficiency caused by, for example, a shortened bowel (stoma) or a disease called SIADH (overproduction of ADH, Antidiuretic Hormone, which leads to too low concentration of sodium in the blood).

How does Natriumklorid Evolan work?

Natriumklorid Evolan contains the salt sodium chloride (common table salt), a substance which is important for the fluid balance.

How is Natriumklorid Evolan used?

The pharmaceutical form of Natriumklorid Evolan is capsule, hard for oral 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 Natriumklorid Evolan have been shown in studies?

As sodium chloride is a well-known substance, and its use in the treatment of sodium deficiency caused by, for example, a shortened bowel (stoma) or a disease called SIADH (overproduction of ADH, Antidiuretic Hormone, which leads to too low concentration of sodium in the blood) is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of sodium chloride in the treatment of sodium deficiency caused by, for example, a shortened bowel (stoma) or a disease called SIADH (overproduction of ADH, Antidiuretic Hormone, which leads to too low concentration of sodium in the blood).

What are the possible side effects of Natriumklorid Evolan?

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

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

Why is Natriumklorid Evolan approved?

The use of Natriumklorid Evolan in the treatment of sodium deficiency caused by, for example, a shortened bowel (stoma) or a disease called SIADH (overproduction of ADH, Antidiuretic Hormone, which leads to too low concentration of sodium in the blood) 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 Natriumklorid Evolan'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 Natriumklorid Evolan?

A risk management plan has been developed to ensure that Natriumklorid Evolan 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 Natriumklorid Evolan, 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 Natriumklorid Evolan

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

This summary was last updated in 2021-04.