LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Movprep Apelsin
(macrogol / ascorbic acid/ sodium sulfate, anhydrous/ sodium ascorbate/ sodium chloride/ potassium chloride)

SE/H/1800/02/E/02

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Summary Public Assessment Report

Movprep Apelsin (Orange)
ascorbic acid, sodium sulfate, anhydrous, sodium ascorbate, sodium chloride, potassium chloride, macrogol

Powder for oral solution

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

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

What is Movprep Apelsin and what is it used for?
Movprep Apelsin is an orange flavoured laxative. Movprep Apelsin is intended for adults to clean the bowel so that they are ready for examination.

How does Movprep Apelsin work?
Movprep Apelsin works by emptying the contents of the bowels, so it is expected to have watery bowel movements.

How is Movprep Apelsin used?

The pharmaceutical form of Movprep Apelsin is powder for oral solution 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 Movprep Apelsin have been shown in studies?

As a line extension, no new preclinical or clinical data has been supplied with this application and this is acceptable for this type of application as reference is made to the dossier for authorised Movprep. It has been shown that Movprep is effective in its intended use for adults to clean the bowel so that they are ready for examination.

What are the possible side effects from Movprep Apelsin?

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 Movprep Apelsin approved?

The Swedish Medical Products Agency decided that Movprep Apelsin’s 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 Movprep Apelsin?

A risk management plan will be submitted within 3 months after the end of the procedure to ensure that Movprep Apelsin is used as safely as possible. Based on this plan, safety information will be included in the summary of product characteristics and the package leaflet for Movprep Apelsin, 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 Movprep Apelsin

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

This summary was last updated in 2021-09.
Infoga datum enligt när sPAR blir klar för publicering.