

Summary Public Assessment Report

Movicol Junior Neutral (macrogol, potassium chloride, sodium chloride, sodium hydrogen carbonate)

SE/H/1799/03/E/01

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macrogol, potassium chloride, sodium chloride, sodium hydrogen carbonate

Powder for oral solution in sachet

This is a summary of the public assessment report (PAR) for Movicol Junior Neutral. 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 Movicol Junior Neutral and what is it used for?

The product is a laxative for the treatment of chronic constipation in children aged 1 to 11 years and for the treatment of very bad constipation (called faecal impaction) in children aged 5 to 11 years.

How does Movicol Junior Neutral work?

Movicol Junior Neutral helps your child to have a comfortable bowel movement even if they have been constipated for a long time.

How is Movicol Junior Neutral used?

The pharmaceutical form is powder for oral solution in sachet 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 Movicol Junior Neutral have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that the product is effective in treating chronic constipation in children aged 1 to 11 years and for the treatment of very bad constipation (called faecal impaction) in children aged 5 to 11 years.

What are the possible side effects from Movicol Junior Neutral?

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 Movicol Junior Neutral 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 Movicol Junior Neutral?

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 Movicol Junior Neutral

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

This summary was last updated in 2022-09.