LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Omnilax
(macrogol)

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Omnilax
(macrogol)

Powder for oral solution in sachet, 10 g

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

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

What is Omnilax and what is it used for?

Omnilax is a 'hybrid generic medicine'. This means that it is similar to a reference medicine containing the same active substance.

The reference medicine for Omnilax is Forlax. Omnilax is used to treat constipation in adults and children aged 8 years and above.

How does Omnilax work?

Omnilax contains the active substance macrogol 4000 and belongs to a group of medicinal products called osmotically acting laxatives. They work by increasing the water content in the stool which helps to relieve problems caused by very slow bowel movements.

How is Omnilax used?

The pharmaceutical form of Omnilax 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.

A prescription might be needed for this medicine.

What benefits of Omnilax have been shown in studies?

Because Omnilax is a hybrid application and is considered to be therapeutically equivalent, to the reference product Forlax, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Omnilax?

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

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

Why is Omnilax approved?

This medicine is similar to a reference medicine containing the same active substance. No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Omnilax'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 Omnilax?

A risk management plan has been developed to ensure that Omnilax 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 Omnilax, 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 Omnilax

The marketing authorisation for Omnilax was granted on 2009-12-11 in Sweden.

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

This summary was last updated in 2018-03-28.