

Summary Public Assessment Report

SmofKabiven Low Osmo Peripheral

(Fish oil (rich in omega-3-acids), olive oil (refined), soya-bean oil (refined), medium-chain triglycerides, glucose monohydrate, alanine, arginine, glycine, histidine, isoleucine, leucine, lysine acetate, methionine, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, calcium chloride dihydrate, sodium glycerophosphate hydrate, magnesium sulphate heptahydrate, potassium chloride, sodium acetate trihydrate and zinc sulphate heptahydrate)

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This is a summary of the public assessment report (PAR) for SmofKabiven Low Osmo Peripheral. It explains how SmofKabiven Low Osmo Peripheral 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 SmofKabiven Low Osmo Peripheral.

For practical information about using SmofKabiven Low Osmo Peripheral, patients should read the package leaflet or contact their doctor or pharmacist.

What is SmofKabiven Low Osmo Peripheral and what is it used for?

SmofKabiven Low Osmo Peripheral can be given to adults and children aged 2 years and above when other forms of feeding are not good enough or have not worked.

How does SmofKabiven Low Osmo Peripheral work?

SmofKabiven Low Osmo Peripheral contains amino acids (components used to build proteins), glucose (carbohydrates), lipids (fat) and salts (electrolytes). SmofKabiven Low Osmo Peripheral provides nutrition when other forms of feeding are not good enough or have not worked.

How is SmofKabiven Low Osmo Peripheral used?

The pharmaceutical form of SmofKabiven Low Osmo Peripheral is an emulsion for infusion given into your blood by a drip (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.

What benefits of SmofKabiven Low Osmo Peripheral have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that SmofKabiven Low Osmo Peripheral is effective in the treatment of adults and children aged 2 years and above when other forms of feeding are not good enough or have not worked.

What are the possible side effects of SmofKabiven Low Osmo Peripheral?

For the full list of all side effects reported with SmofKabiven Low Osmo Peripheral, see section 4 of the package leaflet.

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

Why is SmofKabiven Low Osmo Peripheral approved?

The effect of SmofKabiven Low Osmo Peripheral was established in clinical studies for the treatment of adults and children aged 2 years and above when other forms of feeding are not good enough or have not worked. Therefore, the Medical Products Agency in Sweden decided that the benefits of SmofKabiven Low Osmo Peripheral 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 SmofKabiven Low Osmo Peripheral?

A risk management plan has been developed to ensure that SmofKabiven Low Osmo Peripheral 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 SmofKabiven Low Osmo Peripheral, 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 SmofKabiven Low Osmo Peripheral

The marketing authorisation for SmofKabiven Low Osmo Peripheral was granted on 2019-05-17 in Sweden.

The full PAR for SmofKabiven Low Osmo Peripheral can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with SmofKabiven Low Osmo Peripheral, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2019-06.