

Summary Public Assessment Report

Lipoplus (medium-chain triglycerides, soya-bean oil and omega-3-acid triglycerides)

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(medium-chain triglycerides, soya-bean oil and omega-3-acid triglycerides)

emulsion for infusion, 200 mg/ml

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

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

What is Lipoplus and what is it used for?

Lipoplus 200 mg/ml is used to provide fat to adult patients needing to be fed by an intravenous drip, because they are unable to eat food normally or the normal intake is not enough.

How does Lipoplus work?

Lipoplus 200 mg/ml is an emulsion of oils in water. The oils contained in Lipoplus 200 mg/ml are foodstuffs. They provide energy and contain an essential nutrient, the essential fatty acids omega-6 and omega-3.

How is Lipoplus used?

The pharmaceutical form of Lipoplus is emulsion for 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 Lipoplus have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Lipoplus is effective to provide fat to adult patients needing to be fed by an intravenous drip, because they are unable to eat food normally or the normal intake is not enough.

What are the possible side effects of Lipoplus?

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

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

Why is Lipoplus approved?

It was noted that the effect of Lipoplus to provide fat to adult patients needing to be fed by an intravenous drip, was essentially equivalent to conventional lipid emulsions as regards energy supplementation. Therefore, the Medical Products Agency in Sweden decided that Lipoplus'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 Lipoplus?

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

The marketing authorisation for Lipoplus was granted on 2004-01-16 in Sweden.

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

This summary was last updated in 2015-01.