LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Nutriflex Omega 56/144/40

(Glucose monohydrate, Sodium dihydrogen phosphate dihydrate, Zinc acetate dihydrate, Medium-chain triglycerides, Soya-bean oil, refined, Omega-3-acid triglycerides, Isoleucine, Leucine, Lysine hydrochloride, Methionine, Phenylalanine, Threonine, Tryptophan, Valine, Arginine, Histidine hydrochloride monohydrate, Alanine, Aspartic acid, Glutamic acid, Glycine, Proline, Serine, Sodium hydroxide, Sodium chloride, Sodium acetate trihydrate, Potassium acetate, Magnesium acetate tetrahydrate, Calcium chloride dehydrate)

SE/H/1435/01/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Nutriflex Omega 56/144/40

(Glucose monohydrate, Sodium dihydrogen phosphate dihydrate, Zinc acetate dihydrate, Medium-chain triglycerides, Soya-bean oil, refined, Omega-3-acid triglycerides, Isoleucine, Leucine, Lysine hydrochloride, Methionine, Phenylalanine, Threonine, Tryptophan, Valine, Arginine, Histidine hydrochloride monohydrate, Alanine, Aspartic acid, Glutamic acid, Glycine, Proline, Serine, Sodium hydroxide, Sodium chloride, Sodium acetate trihydrate, Potassium acetate, Magnesium acetate tetrahydrate, Calcium chloride dehydrate)

Emulsion for infusion

This is a summary of the public assessment report (PAR) for Nutriflex Omega 56/144/40. It explains how Nutriflex Omega 56/144/40 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 Nutriflex Omega 56/144/40.

For practical information about using Nutriflex Omega 56/144/40, patients should read the package leaflet or contact their doctor or pharmacist.

What is Nutriflex Omega 56/144/40 and what is it used for?

Nutriflex Omega 56/144/40 contains fluids and substances called amino acids, electrolytes and fatty acids that are essential for the body to grow or to recover. It also contains calories in the form of carbohydrates and fats.

Nutriflex Omega 56/144/40 is given to adults, adolescents and children older than two years.

You are given Nutriflex Omega 56/144/40 when you are unable to eat food normally. There are many situations when this might be the case, for example when you are recovering from surgery, injuries, or burns, or when you are unable to absorb food from your stomach and gut.

How does Nutriflex Omega 56/144/40 work?

Nutriflex Omega 56/144/40 contains fluids and substances called amino acids, electrolytes and fatty acids that are essential for the body to grow or to recover. It also contains calories in the form of carbohydrates and fats.

How is Nutriflex Omega 56/144/40 used?

The pharmaceutical form of Nutriflex Omega 56/144/40 is emulsion for infusion and is administered by intravenous infusion (drip), that is, through a small tube directly into a vein.

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 Nutriflex Omega 56/144/40 have been shown in studies?

The company provided data on efficacy and safety. These data have shown that Nutriflex Omega 56/144/40 is effective for supply of energy through parenteral nutrition of patients in states of moderate to severe catabolism when oral or enteral nutrition is impossible, insufficient or contraindicated.

What are the possible side effects of Nutriflex Omega 56/144/40?

For the full list of all side effects reported with Nutriflex Omega 56/144/40, see section 4 of the package leaflet.

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

Why is Nutriflex Omega 56/144/40 approved?

The company provided data on efficacy and safety that supported the indication and no new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Nutriflex Omega 56/144/40'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 Nutriflex Omega 56/144/40?

A risk management plan has been developed to ensure that Nutriflex Omega 56/144/40 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 Nutriflex Omega 56/144/40, 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 Nutriflex Omega 56/144/40

The marketing authorisation for Nutriflex Omega 56/144/40 was granted on 2016-12-09 in Sweden.

The full PAR for Nutriflex Omega 56/144/40 can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Nutriflex Omega 56/144/40, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2024-02.