

Summary Public Assessment Report

Quatriga Low Osmo Peripheral

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

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Emulsion for infusion

This is a summary of the public assessment report (PAR) for Quatriga Low Osmo Peripheral. 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 Quatriga Low Osmo Peripheral and what is it used for?

Quatriga Low Osmo Peripheral is an emulsion for infusion given into the blood by a drip (intravenous infusion). The product contains amino acids (components used to build proteins), glucose (carbohydrates), lipids (fat) and salts (electrolytes) in a plastic bag.

The product is used as parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated.

How does Quatriga Low Osmo Peripheral work?

When other forms of feeding are not good enough or have not worked, Quatriga Low Osmo Peripheral can be used to compensate for this.

How is Quatriga Low Osmo Peripheral used?

The pharmaceutical form is emulsion for infusion given into the 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 in Sweden.

What benefits of Quatriga Low Osmo Peripheral 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:

Parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated.

What are the possible side effects from Quatriga Low Osmo Peripheral?

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 Quatriga Low Osmo Peripheral 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 Quatriga Low Osmo Peripheral?

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 Quatriga Low Osmo Peripheral

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

This summary was last updated in 2022-09.