

Summary Public Assessment Report

Quatriga extra Nitrogen

(alanine, arginine, glycine, histidine, isoleucine, leucine, lysine acetate, methionine, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, calcium chloride dehydrate, 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)

Quatriga extra Nitrogen Electrolyte free

(alanine, arginine, glycine, histidine, isoleucine, leucine, lysine acetate, methionine, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, glucose monohydrate, soya-bean oil refined, triglycerides medium chain, olive oil refined, fish oil rich in omega-3-acids)

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Quatriga extra Nitrogen Electrolyte free

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Intravenous infusion

This is a summary of the public assessment report (PAR) for Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free.

It explains how Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free were assessed and their authorisations recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free.

For practical information about using Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free, patients should read the package leaflet or contact their doctor or pharmacist.

What are Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free and what are they used for?

Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free are medicines with 'well-established use'. This means that the medicinal use of the active substances of Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free are well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free are used for parenteral nutrition and can be given to adults and children aged 2 years and above.

How do Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free work?

Quatriga extra Nitrogen Electrolyte free and Quatriga extra Nitrogen are emulsions for infusion given into your blood by a drip (intravenous infusion). The product contains amino

acids (components used to build proteins), glucose (carbohydrates) and lipids (fat) in a plastic bag.

How are Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free used?

The pharmaceutical form of Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free 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 Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free have been shown in studies?

As the active substances are well-known, and its use as parenteral nutrition is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of the active substances.

What are the possible side effects of Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free?

For the full list of all side effects reported with Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free, see section 4 of the package leaflet.

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

Why are Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free approved?

The use of Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free as parenteral nutrition is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free 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 Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free?

A risk management plan has been developed to ensure that Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free are 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 Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free, 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 extra Nitrogen and Quatriga extra Nitrogen Electrolyte free

The marketing authorisation for Quatriga extra Nitrogen and Quatriga extra Nitrogen Electrolyte free were granted on 2018-10-15 in Sweden.

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

This summary was last updated in 2018-11.