

Summary Public Assessment Report

SmofKabiven extra Nitrogen

Active substances:

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

SmofKabiven extra Nitrogen Electrolyte free

Active substances:

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

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Summary Public Assessment Report

SmofKabiven extra Nitrogen, emulsion for infusion

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

SmofKabiven extra Nitrogen Electrolyte free, emulsion for infusion

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

This is a summary of the public assessment report (PAR) for SmofKabiven extra Nitrogen and SmofKabiven extra Nitrogen Electrolyte free. It explains how SmofKabiven extra Nitrogen and SmofKabiven extra Nitrogen Electrolyte free 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 extra Nitrogen and SmofKabiven extra Nitrogen Electrolyte free.

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

What is SmofKabiven extra Nitrogen and SmofKabiven extra Nitrogen Electrolyte free and what is it used for?

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

SmofKabiven extra Nitrogen and SmofKabiven extra Nitrogen Electrolyte free 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 extra Nitrogen and SmofKabiven extra Nitrogen Electrolyte free work?

SmofKabiven extra Nitrogen contains amino acids (components used to build proteins), glucose (carbohydrates), lipids (fat) and salts (electrolytes) while SmofKabiven extra Nitrogen Electrolyte free contains the same apart from the salts (electrolytes). SmofKabiven extra Nitrogen and SmofKabiven extra Nitrogen Electrolyte free provides nutrition when other forms of feeding are not good enough or have not worked.

How is SmofKabiven extra Nitrogen and SmofKabiven extra Nitrogen Electrolyte free used?

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

As the active substances (see list above) of SmofKabiven extra Nitrogen and SmofKabiven extra Nitrogen Electrolyte free are well-known substances, and their use 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, is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of the active substances 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 extra Nitrogen and SmofKabiven extra Nitrogen Electrolyte free?

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

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

Why is SmofKabiven extra Nitrogen and SmofKabiven extra Nitrogen Electrolyte free approved?

The use of SmofKabiven extra Nitrogen and SmofKabiven extra Nitrogen Electrolyte free 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, 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 SmofKabiven extra Nitrogen and SmofKabiven extra Nitrogen Electrolyte free'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 SmofKabiven extra Nitrogen and SmofKabiven extra Nitrogen Electrolyte free?

A risk management plan has been developed to ensure that SmofKabiven extra Nitrogen and SmofKabiven extra Nitrogen Electrolyte free 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 extra Nitrogen and SmofKabiven 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 SmofKabiven extra Nitrogen and SmofKabiven extra Nitrogen Electrolyte free

The marketing authorisation for SmofKabiven extra Nitrogen and SmofKabiven extra Nitrogen Electrolyte free was granted on 2017-07-07 in Sweden.

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

This summary was last updated in 2017-07.