Package leaflet: Information for the patient

Infutraze concentrate for solution for infusion

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If your child gets any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Infutraze is and what it is used for

Infutraze is a mixture of trace elements given into the blood by a drip (intravenous infusion). Infutraze contains five trace elements (zinc, copper, manganese, selenium, and iodine) in very small amounts which are normally absorbed from food. These trace elements are necessary for a normal body function.

Infutraze is used to meet the basic requirements of trace elements for preterm and term neonates, infants, children, and adolescents who cannot eat or absorb enough food through tube feeding and thus need food infused through their vein (called intravenous nutrition or parenteral nutrition). Infutraze is added to parenteral nutrition containing all the nutrients the body needs.

2. What you need to know before use of Infutraze

Do not use Infutraze if your child:
- is allergic (hypersensitive) to the active substances or any of the other ingredients of this medicine (listed in section 6)
- has Wilson's disease.

Warnings and precautions
Talk to your doctor before using Infutraze if your child has :
- kidney problems
- liver problems
- reduced biliary excretion
- thyroid problems (hyperthyroidism)

Blood levels of trace elements will be monitored regularly by your doctor during treatment. Your doctor will adapt the dosage of Infutraze accordingly.

Children and adolescents
Infutraze is for preterm and term neonates, infants, children, and adolescents.

Other medicines and Infutraze
Tell your doctor if your child is taking, has recently taken, or might take any other medicines.

Pregnancy and breastfeeding
If your child is pregnant or is breastfeeding, ask your doctor for advice before using Infutraze.

Infutraze contains sodium and potassium
Infutraze contains less than 1 mmol sodium (23 mg) per 10 ml ampoule, that is to say essentially 'sodium-free'.
Infutraze contains less than 1 mmol potassium (39 mg) per 10 ml ampoule, that is to say essentially 'potassium-free'.

3. How to use Infutraze

Infutraze will be given to your child as an intravenous infusion (into the blood by a drip) by a healthcare professional. Infutraze will always be given diluted in another parenteral nutrition solution.

Your doctor will decide on the individual dose for your child depending on body weight and function.

A daily iron infusion is recommended when parenteral nutrition is given for more than 3 weeks, and molybdenum should be infused in addition when parenteral nutrition is given for more than 4 weeks.

If more Infutraze was given than it should
It is unlikely that your child will receive too much of Infutraze as the infusion will be monitored by a healthcare professional. If you think your child has received too much Infutraze, inform your doctor.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

No side effects have been reported.

Reporting of side effects
If your child gets any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

United Kingdom
Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Infutraze

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Do not freeze.

Do not use this medicine if you notice visible signs of deterioration.

Do not use this medicine after the expiry date which is stated on the carton and ampoule label after EXP. The expiry date refers to the last day of that month.

Shelf life after mixing
In-use stability after mixing has been demonstrated for up to 7 days at 2-8°C followed by 48 hours at 20°C-25°C, including duration of administration. From a microbiological point of view, the product should be used immediately. If not used immediately, the in-use storage time and conditions prior to use are the responsibility of the user and should normally not be longer than 24 hours at 2-8°C.

6. Contents of the pack and other information

What Infutraze contains

The active substances are:

Infutraze	1 ml	1 ampoule (10 ml)
Zinc chloride	1042 micrograms	10420 micrograms
Copper chloride dihydrate	107.4 micrograms	1074 micrograms
Manganese chloride tetrahydrate	3.600 micrograms	36.00 micrograms
Sodium selenite	15.33 micrograms	153.3 micrograms
Potassium iodide	2.567 micrograms	25.67 micrograms

The active ingredients in 1 ml of Infutraze correspond to:

Zinc (Zn)	7.64 micromoles	500 micrograms
Copper (Cu)	0.630 micromoles	40.0 micrograms
Manganese (Mn)	0.0182 micromoles	1.00 micrograms
Selenium (Se)	0.0887 micromoles	7.00 micrograms
Iodine (I)	0.0155 micromoles	1.96 micrograms

The other ingredients are
Hydrochloric acid (for pH-adjustment)
Water for injections

What Infutraze looks like and contents of the pack

Infutraze, concentrate for solution for infusion is clear and almost colourless. It comes in 10 ml transparent ampoules made of polypropylene.

Pack size:
20 x 10 ml in a cardboard box

Marketing Authorisation Holder and Manufacturer

Manufacturer:
Fresenius Kabi Norge AS
Svinesundsveien 80
NO-1788 Haden
Norway

Marketing authorisation holder:
Ireland
Fresenius Kabi Deutschland GmbH
Else-Kroner-Strasse 1
61362 Bad Homburg v.d.h
Germany

United Kingdom
Fresenius Kabi Limited
Cestrian Court, Eastgate Way
Manor Park
Runcorn, Cheshire
WA7 1NT
United Kingdom

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria	Kidtrayze Konzentrat zur Herstellung einer Infusionslösung
Belgium	Kidtrayze concentraat voor oplossing voor infusie Kidtrayze solution à diluer pour perfusion Kidtrayze Konzentrat zur Herstellung einer Infusionslösung
Bulgaria	Педитрейс Новум концентрат за инфузионен разтвор Peditrace Novum concentrate for solution for infusion
Croatia	Peditrace Novum koncentrat za otopinu za infuziju
Cyprus	Kidtrayze πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση
Czech Republic	Peditrace Novum
Denmark	Peditrace Novum
Estonia	Infutraze
Finland	Kidtrayze
France	Peditrace solution à diluer pour perfusion
Germany	Kidtrayze Konzentrat zur Herstellung einer Infusionslösung
Greece	Kidtrayze πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση
Hungary	Infutraze koncentrátum oldatos infúzióhoz
Iceland	Peditrace Novum
Italy	Kidtrayze
Ireland	Infutraze concentrate for solution for infusion
Latvia	Infutraze koncentrāts infūziju šķīduma pagatavošanai
Lithuania	Infutraze koncentratas infuziniam tirpalui
Luxembourg	Kidtrayze
Malta	Kidtrayze concentrate for solution for infusion
Netherlands	Kidtrayze concentraat voor oplossing voor infusie
Norway	Kidtrayze
Poland	Peditrace Novum
Portugal	Kidtrayze
Romania	Kidtrayze concentrat pentru soluție perfuzabilă
Slovakia	Peditrace
Slovenia	Kidtrayze koncentrat za raztopino za infundiranje
Spain	Infutraze
Sweden	Peditrace Novum
United Kingdom (Northern Ireland)	Infutraze concentrate for solution for infusion

This leaflet was last revised in January 2024.

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The following information is intended for healthcare professionals only:

Special warnings and precautions for use

Infutraze should be used with caution in patients with impaired renal function, in whom the excretion of selenium, zinc and iodine may be significantly decreased. There is an increased risk of trace element accumulation in those patients.

Infutraze should be used with caution in patients with liver dysfunction (especially cholestasis) in whom excretion of copper and manganese may be decreased.

In patients with impaired biliary excretion, elimination of manganese, copper, and zinc may be reduced. Clinical signs of trace element accumulation may require dose reduction or interruption of Infutraze use in those patients.

Dose adjustments might be needed in patients with impaired renal function and impaired liver function or mild cholestasis.

Infutraze should be used with caution in patients with hyperthyroidism. In those patients, iodine may increase symptoms of hyperthyroidism (e.g., goitre).

No adjustment of Infutraze is required in case of additional intake of iodine through iodine-based antiseptic.

Long-term parenteral nutrition
In patients receiving long-term parenteral nutrition, accumulation of trace elements might occur, especially of manganese. If the treatment is continued for more than 4 weeks, manganese levels should be monitored. The occurrence of neurological signs (e.g., anxiety, rapid eye movements) may indicate possible manganese overload which may also arise from certain medical conditions and from parenteral nutrition. Manganese accumulation may require dose reduction or interruption of Infutraze use.
In patients receiving long-term parenteral nutrition, trace element deficiency might occur, especially for copper, zinc, and selenium. In case of deficiency, those individual trace elements should be supplied separately.

Posology

Preterm neonates:
A recommended maximum daily dose of 1.0 mL Infutraze per kg body weight covers basal requirements of the included trace elements.

Term neonates, infants, and children weighing less than 20 kg:
A recommended maximum daily dose of 0.5 mL Infutraze per kg body weight covers basal requirements of the included trace elements.

Children weighing more than 20 kg and adolescents:
A recommended maximum daily dose of 10 mL Infutraze covers basal requirements of the included trace elements.

The following trace element amounts are contained in 0.5 ml, 1.0 ml, and 10 ml Infutraze:

	0.5 ml	1.0 ml	10 ml
Zn	250 micrograms	500 micrograms	5000 micrograms
Cu	20.0 micrograms	40.0 micrograms	400 micrograms
Mn	0.50 micrograms	1.00 micrograms	10.0 micrograms

Se	3.50 micrograms	7.00 micrograms	70.0 micrograms
I	0.98 micrograms	1.96 microgram	19.6 micrograms

In addition to the trace elements contained in Infutraze, daily iron infusions are recommended if patients receive parenteral nutrition for more than 3 weeks. Addition of molybdenum to parenteral nutrition is recommended if patients receive parenteral nutrition for more than 4 weeks.

Method of administration

Infutraze must not be given undiluted. Infutraze shall be given as an intravenous infusion, diluted in a parenteral nutrition solution/emulsion. The rate and duration of infusion is determined by the rate and duration of infusion of the parenteral nutrition solution.

Infutraze may only be mixed with other nutritional products for which compatibility has been documented, see section Compatibility below.

Special precautions for disposal and other handling

Before use, visually check that the concentrate for solution for infusion is clear and free of particles.

Compatibility
Dilute before use.
Infutraze is used as an additive to parenteral nutrition admixtures where compatibility data are available.

Compatibility data are available with the named branded products Aminoven Infant, Vaminolact, Vamin 14 EF, Vamin 18 EF, SMOFlipid, Intralipid, Vitalipid N Adult, Vitalipid N Infant, Solivito N, Addiphos and Sodium Glycerophosphate in defined amounts, combined with generics of glucose and electrolytes in defined concentrations. Peditrace Novum can also be added to SmofKabiven and SmofKabiven EF with or without Vitalipid N Infant/Adult, Solivito N and electrolytes.

Generated data supports additions according to the summary table below:

Infutraze	**Admixture**
0-10 ml/L	Aqueous PN admixtures with the components listed above
0-10 ml/L	Lipid-containing PN admixtures with the components listed above
0-10 mL	SmofKabiven and SmofKabiven EF (activated 986 mL, 1477 mL, 1970 mL or 2463 mL bag) with electrolytes and vitamins as listed above
0-5 mL	SmofKabiven and SmofKabiven EF (activated 493 mL bag) with electrolytes and vitamins as listed above

Infutraze should never be added directly to a lipid emulsion because of the destabilising effects. It is recommended that the macronutrients (amino acid solution and glucose with or without lipid emulsion) are mixed first, before adding the micronutrients. Additions should be made aseptically.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Shelf life after mixing

In-use stability after mixing (see section compatibility) has been demonstrated for up to 7 days at 2-8°C followed by 48 hours at 20°C-25°C, including duration of administration. From a microbiological point of view, the product should be used immediately. If not used immediately, the in-use storage time and conditions prior to use are the responsibility of the user and should normally not be longer than 24 hours at 2-8°C.