Package leaflet: Information for the user

# NUTRYELT®

## Concentrate for solution for infusion

AGUETTANT

**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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of this medicinal product is NUTRYELT®, concentrate for solution for infusion, but will be referred as NUTRYELT® throughout the whole leaflet.

**What is in this leaflet:**


## 1. WHAT NUTRYELT® IS AND WHAT IT IS USED FOR

NUTRYELT® is a concentrate for solution for infusion.
It contains 9 essential trace elements (iron, copper, manganese, zinc, fluorine, iodine, selenium, chromium, molybdenum).
These trace elements are considered as essential because the body cannot produce them but needs them in very small quantities in order to function properly.
NUTRYELT® is used to provide trace elements in adults needing intravenous (into a vein) feeding.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU USE NUTRYELT®

**Do not use NUTRYELT®:**
- if you are allergic (hypersensitive) to any of the ingredients of NUTRYELT® (see section 6 of this leaflet).
- if you have abnormally high level of any of the ingredients of the product in your blood. (If you have any doubt, ask your doctor).
- if you have a pronounced cholestasis (yellowing of the skin or whites of the eyes caused by liver or blood problem).
- if you have an excess of copper (Wilson´s disease) or iron in the body (hemochromatosis).

**Warnings and precautions**
Talk to your doctor or pharmacist before using NUTRYELT® if:
- you have kidney problems,
- you have liver problems such as mild cholestasis (impaired liver function with a yellowing of the skin or whites of eyes),
- you receive repeated blood transfusions,
- you have diabetes and are on insulin medication,
- you have thyroid problems, or if you are taking iodine-containing medicines (e.g. iodine antiseptics).

Blood levels of trace elements will be monitored regularly by your doctor during the treatment, and your doctor will adapt the dosage of NUTRYELT® accordingly.

**Children**
NUTRYELT® must not be used in children and adolescents.

**Other medicines and NUTRYELT®**
Tell your doctor if you are taking, have recently taken or might take any other medicines. Particularly iron salts (oral route).

**Pregnancy and Breast-feeding**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before taking this medicine.
NUTRYELT® should not be used during pregnancy and lactation unless the doctor considers it absolutely necessary.

**NUTRYELT® contains sodium and potassium**
This medicinal product contains less than 1 mmol sodium (23 mg) per ampoule, i.e. essentially “sodium-free”.
This medicinal product contains less than 1 mmol potassium (39 mg) per ampoule, i.e. essentially “potassium-free”.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 3. HOW TO USE NUTRYELT®

NUTRYELT® is intended for adult patients only.
NUTRYELT® will be given to you intravenously (into a vein) by a nurse or doctor. Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

**Instructions for dilution of NUTRYELT® before administration**
NUTRYELT® is not intended to be administered in its current presentation.
NUTRYELT® must be diluted or mixed with gentle agitation during preparation under strict aseptic conditions, before infusion.
NUTRYELT® must be diluted with respect to the final appropriate osmolarity.
For example:
- 10 to 20 ml of NUTRYELT® can be diluted in at least 250 ml of Sodium Chloride 0.9 % solution for infusion,
- 10 to 20 ml of NUTRYELT can be diluted in at least 250 ml of Glucose 5% solution for infusion.

The pH after reconstitution of 20 ml of NUTRYELT® with 250 ml Sodium chloride 0.9% will be 3.3, or 3.3-3.4 with Glucose 5%.
The reconstituted solution for infusion has to be visually inspected prior to use.
Only clear solution without particles should be used.
Do not store partly used containers and discard all equipment after use.
The compatibility with solutions administered simultaneously via a common inlet cannula must be ensured.
Degradation of ascorbic acid in parenteral nutrition mix is accelerated by trace elements.
This medicinal product must not be mixed with other medicinal products except those mentioned in this section.
NUTRYELT® must not be used as a vehicle for other drugs.

**Dosage**
Your doctor will determine the right dosage for you.
The recommended daily dose is one ampoule (10 ml) of NUTRYELT®. Your doctor can give you up to 2 ampoules per day.

**Use in children**
NUTRYELT® must not be used in children and adolescents.
A product specific for children and adolescents should be used to provide them with trace elements when they need intravenous (into a vein) feeding.

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## TECHNICAL LEAFLET

### NUTRYELT®, concentrate for solution for infusion

**The following information is intended for medicinal and healthcare professional only.**

**Qualitative and Quantitative composition**

| Composition for 1000 ml NUTRYELT® | | Content per ampoule of 10 ml | |
|---|---|---|---|
| Zinc gluconate | 6970.0 mg | Zinc (Zn) | 10000 µg |
| Copper gluconate | 214.24 mg | Copper (Cu) | 300 µg |
| Manganese gluconate | 44.569 mg | Manganese (Mn) | 55 µg |
| Sodium fluoride | 209.95 mg | Fluorine (F) | 950 µg |
| Potassium iodide | 17.006 mg | Iodine (I) | 130 µg |
| Sodium selenite | 15.332 mg | Selenium (Se) | 70 µg |
| Sodium molybdate | 4.293 mg | Molybdenum (Mo) | 20 µg |
| Chromium chloride | 3.045 mg | Chromium (Cr) | 10 µg |
| Ferrous gluconate | 798. 82 mg | Iron (Fe) | 1000 µg |

Density: 1.0
pH: 2.6 to 3.2
Osmolality: 60 to 100 mosm/kg
Osmolarity: 60 to 100 mosm/l

List of excipients: Hydrochloric acid, water for Injections

**Description of solution:** Clear, limpid and slightly yellow solution.

**Posology and method of administration:** For adults only.
The recommended daily dose in patients with basal to moderately increased requirements is one ampoule (10 ml) of NUTRYELT®.
In cases of significantly increased trace element requirements (such as extensive burns, patients in severe hypercatabolic state due to major trauma) 2 ampoules (20 ml) of NUTRYELT® may be given per day, and monitoring of serum trace element level is recommended.
In patients with renal, hepatic impairments or mild cholestasis the posology should be adapted.
*Paediatric population:* NUTRYELT® is contraindicated in children and adolescents.
A specific paediatric product should be used for trace element supplementation in the paediatric population during parenteral nutrition.

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**If you take more NUTRYELT® than you should**
Your doctor will stop your treatment with NUTRYELT® and do the necessary laboratory tests in the case of suspected overdose.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Tell your doctor if you notice any of the following:
Frequency not known (cannot be estimated from the available data):
pain at the application site.
Cases of hypersensitivity reactions including fatal anaphylactic reactions have been reported in patients receiving IV iron-containing products.
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:
**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.
By reporting side effects you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE NUTRYELT®

After dilution, chemical and physical in-use stability has been demonstrated for 48 h at 25°C, protected from light.
From a microbiological point of view, the product should be used immediately after dilution. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.
Keep this medicine out the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Do not freeze.
Keep the container in the outer carton in order to protect from light.
Before use, check that the concentrate for solution for infusion is homogeneous and that the bottle is not damaged and is free of particles.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

**What NUTRYELT® contains**
The active substances are:
For 10 ml NUTRYELT®

| | | |
|---|---|---|
| Zinc (Zn) | 10000 µg | (as Zinc gluconate) |
| Copper (Cu) | 300 µg | (as Copper gluconate) |
| Manganese (Mn) | 55 µg | (as Manganese gluconate) |
| Fluorine (F) | 950 µg | (as Sodium fluoride) |
| Iodine (I) | 130 µg | (as Potassium iodide) |
| Selenium (Se) | 70 µg | (as Sodium selenite) |
| Molybdenum (Mo) | 20 µg | (as Sodium molybdate) |
| Chromium (Cr) | 10 µg | (as Chromium chloride) |
| Iron (Fe) | 1000 µg | (as Ferrous gluconate) |

pH: 2.6 to 3.2
Osmolarity: 60 to 100 mosm/L
The other ingredients are hydrochloric acid and water for injections.

**What NUTRYELT® looks like and contents of the pack**
NUTRYELT® is a clear, limpid and slightly yellow concentrate for solution for infusion in a 10 ml ampoule.
NUTRYELT® is packed in boxes of 4, 10, 25 and 50 ampoules.
Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**
**Marketing Authorisation Holder**
Laboratoire Aguettant
1 rue Alexander Fleming
69007 LYON
France
**Manufacturer**
Laboratoire AGUETTANT
Lieu-dit « Chantecaille »
07340 CHAMPAGNE-SERRIERES
France
**Distributed by**
Baxter Healthcare Limited
Caxton Way, Thetford, Norfolk, IP24 3SE
United Kingdom

**This medicinal product is authorised in the Member States of the EEA under the following names:**

| | |
|---|---|
| **Austria** | NUTRYELT®, Konzentrat zur Herstellung einer Infusionslosung |
| **Belgium** | NUTRYELT®, solution à diluer pour perfusion / Konzentrat zur Herstellung einer Infusionslosung / Concentraat voor oplossing voor infusie |
| **Czech Republic** | NUTRYELT®, Koncentrát pro infuzní roztok |
| **Denmark** | Nutryelt |
| **Finland** | NUTRYELT®, infuusiokonsentraatti, liuosta varten |
| **France** | NUTRYELT®, solution à diluer pour perfusion |
| **Germany** | ADDEL TRACE®, Konzentrat zur Herstellung einer Infusionslosung |
| **Italy** | SUPPLYELT® |
| **Luxembourg** | NUTRYELT®, solution à diluer pour perfusion |
| **Netherlands** | NUTRYELT®, concentraat voor oplossing voor infusie |
| **Norway** | NUTRYELT®, Konsentrat til infusjonsvæske, oppløsning |
| **Poland** | NUTRYELT® |
| **Portugal** | NUTRYELT® |
| **Sweden** | Nutryelt®, koncentrat till infusionsvätska, lösning |
| **United-Kingdom** | NUTRYELT®, concentrate for solution for infusion |

**This leaflet was last revised in 08/2019.**

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Method of administration
NUTRYELT® is not intended to be administered in its current presentation. It should be diluted according to the final desired osmolarity. The osmolarity value of the final preparation allows either administration through a peripheral vein, or only central venous catheter administration.

**Pharmaceutical Particulars**
Incompatibilities
• NUTRYELT® must not be used as a vehicle for other drugs.
• NUTRYELT®, as with other trace element solutions, cannot be added directly to inorganic phosphate (additive) solutions.
• Degradation of ascorbic acid in parenteral nutrition mix is accelerated by trace elements.
This medicinal product must not be mixed with other medicinal products except sodium chloride 0.9% and glucose 5%.
Shelf life
3 years.
After dilution, chemical and physical in-use stability has been demonstrated for 48 h at 25°C protected from light. From a microbiological point of view, the product should be used immediately after dilution. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.
Special precaution for storage
Do not freeze.
Keep the container in the outer carton in order to protect from light.
Nature and content of container
10 ml solution in polypropylene ampoule in pack sizes of 4, 10, 25 and 50.
Instructions for use and handling and disposal
Before use, check that the concentrate for solution for infusion is homogeneous and that the bottle is not damaged and is free of particles.
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