

## **Package leaflet: Information for the user**

### **SUPPLYELT, 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, 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 SUPPLYELT, concentrate for solution for infusion, but will be referred as SUPPLYELT throughout the whole leaflet

What is in this leaflet

1. What SUPPLYELT is and what it is used for
2. What you need to know before you use SUPPLYELT
3. How to use SUPPLYELT
4. Possible side effects
5. How to store SUPPLYELT
6. Contents of the pack and other information

#### **1. What SUPPLYELT is and what it is used for**

SUPPLYELT 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.

SUPPLYELT is used to provide trace elements in adults needing intravenous (into a vein) feeding.

#### **2. What you need to know before you use SUPPLYELT**

##### **Do not use SUPPLYELT:**

- if you are allergic (hypersensitive) to any of the ingredients of SUPPLYELT (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 SUPPLYELT 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 SUPPLYELT accordingly.

### **Children**

SUPPLYELT must not be used in children and adolescents.

### **Other medicines and SUPPLYELT**

Tell your doctor if you are taking, have recently taken or might take any other medicines. Particularly Iron salts (oral route).

### **SUPPLYELT and alcohol**

Not applicable

### **Pregnancy and Breastfeeding**

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.

SUPPLYELT should not be used during pregnancy and lactation unless the doctor considers it absolutely necessary.

### **Driving and using machines**

Not applicable

### **SUPPLYELT 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 SUPPLYELT**

SUPPLYELT is intended for adult patients only.

SUPPLYELT 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 SUPPLYELT before administration**

SUPPLYELT is not intended to be administered in its current presentation. SUPPLYELT must be diluted or mixed with gentle agitation during preparation under strict aseptic conditions, before infusion.

SUPPLYELT must be diluted with respect to the final appropriate osmolarity. For example:

- 10 to 20 ml of Supplyelt can be diluted in at least 250 ml of Sodium Chloride 0.9 % solution for infusion,
- 10 to 20 ml of Supplyelt can be diluted in at least 250 ml of Glucose 5% solution for infusion

The pH after reconstitution of 20 ml of Supplyelt 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.

SUPPLYELT 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 SUPPLYELT. Your doctor can give you up to 2 ampoules per day.

### **Use in children**

SUPPLYELT 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.

### **If you take more SUPPLYELT than you should**

Your doctor will stop your treatment with SUPPLYELT and do the necessary laboratory tests in the case of suspected overdose.

### **If you stop taking SUPPLYELT**

Not applicable

## **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.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or, 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:

#### **Ireland**

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: [www.hpra.ie](http://www.hpra.ie)

e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store SUPPLYELT**

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 SUPPLYELT contains

The active substances are:

For 10 ml SUPPLYELT

Zinc (Zn)	10000 micrograms	(as Zinc gluconate)
Copper (Cu)	300 micrograms	(as Copper gluconate)
Manganese (Mn)	55 micrograms	(as Manganese gluconate)
Fluorine (F)	950 micrograms	(as Sodium fluoride)
Iodine (I)	130 micrograms	(as Potassium iodide)
Selenium (Se)	70 micrograms	(as Sodium selenite)
Molybdenum (Mo)	20 micrograms	(as Sodium molybdate)
Chromium (Cr)	10 micrograms	(as Chromium chloride)
Iron (Fe)	1000 micrograms	(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 SUPPLYELT looks like and contents of the pack

SUPPLYELT is a clear, limpid and slightly yellow concentrate for solution for infusion in a 10 ml ampoule.

SUPPLYELT is packed in boxes of 10, 25 and 50 ampoules.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing authorization 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:**

<b>Austria</b>	NUTRYELT, Konzentrat zur Herstellung einer Infusionslösung
<b>Belgium</b>	NUTRYELT, solution à diluer pour perfusion / Konzentrat zur Herstellung einer Infusionslösung / Concentraat voor oplossing voor infusie
<b>Czech Republic</b>	NUTRYELT, Koncentrát pro infuzní roztok
<b>Denmark</b>	Nutryelt
<b>Finland</b>	NUTRYELT, infuusiokonsentraatti, liuosta varten
<b>France</b>	NUTRYELT, solution à diluer pour perfusion
<b>Germany</b>	ADDEL TRACE, Konzentrat zur Herstellung einer Infusionslösung
<b>Greece</b>	NUTRYELT, πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση
<b>Ireland</b>	SUPPLYELT, concentrate for solution for infusion
<b>Italy</b>	SUPPLYELT
<b>Luxembourg</b>	NUTRYELT, solution à diluer pour perfusion
<b>Netherlands</b>	NUTRYELT, concentraat voor oplossing voor infusie
<b>Norway</b>	NUTRYELT, Konsentrat til infusjonsvæske, oppløsning
<b>Poland</b>	NUTRYELT
<b>Portugal</b>	NUTRYELT
<b>Spain</b>	NUTRYELT, concentrado para solución para perfusión
<b>Sweden</b>	Nutryelt, koncentrat till infusionsvätska, lösning
<b>United-Kingdom</b>	NUTRYELT, concentrate for solution for infusion

**This leaflet was last revised in**

## TECHNICAL LEAFLET

### SUPPLYELT, concentrate for solution for infusion

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

- **Qualitative and Quantitative composition**

- Composition for 1000 ml SUPPLYELT

Zinc gluconate	6970.0 mg
Copper gluconate	214.24 mg
Manganese gluconate	44.569 mg
Sodium fluoride	209.95 mg
Potassium iodide	17.006 mg
Sodium selenite	15.332 mg
Sodium molybdate	4.293 mg
Chromium chloride	3.045 mg
Ferrous gluconate	798.82 mg
Density	1.0
pH	2.6 to 3.2
Osmolality	60 to 100 mosm/kg
Osmolarity	60 to 100 mosm/l

- Content per ampoule of 10 ml

Zinc (Zn)	10000 micrograms
Copper (Cu)	300 micrograms
Manganese (Mn)	55 micrograms
Fluorine (F)	950 micrograms
Iodine (I)	130 micrograms
Selenium (Se)	70 micrograms
Molybdenum (Mo)	20 micrograms
Chromium (Cr)	10 micrograms
Iron (Fe)	1000 micrograms

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 SUPPLYELT.

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 SUPPLYELT 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*

SUPPLYELT is contraindicated in children and adolescents.

A specific paediatric product should be used for trace element supplementation in the paediatric population during parenteral nutrition.

#### Method of administration

SUPPLYELT 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

- SUPPLYELT must not be used as a vehicle for other drugs.
- SUPPLYELT, 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 10, 25 and 50.

- Instructions for use and handling and disposal

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