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, fluoride, 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 your body weight is less than 40 kg.
- 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.

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

Children
SUPPLYELT® must not be used in children.

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).

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
This medicinal product contains less than 1 mmol sodium (1.2 mg) per ampoule, i.e. essentially "sodium-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.

TECHNICAL LEAFLET
SUPPLYELT, concentrate for solution for infusion

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

Qualitative and Quantitative composition

<table>
<thead>
<tr>
<th>Composition for 1000 ml SUPPLYELT</th>
<th>Content per ampoule of 10 ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc gluconate</td>
<td>6970.0 mg</td>
</tr>
<tr>
<td>Copper gluconate</td>
<td>214.24 mg</td>
</tr>
<tr>
<td>Manganese gluconate</td>
<td>44.569 mg</td>
</tr>
<tr>
<td>Sodium fluoride</td>
<td>209.95 mg</td>
</tr>
<tr>
<td>Potassium iodide</td>
<td>17.006 mg</td>
</tr>
<tr>
<td>Sodium selenite</td>
<td>15.332 mg</td>
</tr>
<tr>
<td>Sodium molybdate</td>
<td>4.293 mg</td>
</tr>
<tr>
<td>Chromium chloride</td>
<td>3.045 mg</td>
</tr>
<tr>
<td>Ferrous gluconate</td>
<td>798.82 mg</td>
</tr>
<tr>
<td>Zine (Zn)</td>
<td>10000 micrograms</td>
</tr>
<tr>
<td>Copper (Cu)</td>
<td>300 micrograms</td>
</tr>
<tr>
<td>Manganese (Mn)</td>
<td>55 micrograms</td>
</tr>
<tr>
<td>Fluorine (F)</td>
<td>930 micrograms</td>
</tr>
<tr>
<td>Iodine (I)</td>
<td>130 micrograms</td>
</tr>
<tr>
<td>Selenium (Se)</td>
<td>70 micrograms</td>
</tr>
<tr>
<td>Molybdenum (Mo)</td>
<td>20 micrograms</td>
</tr>
<tr>
<td>Chromium (Cr)</td>
<td>18 micrograms</td>
</tr>
<tr>
<td>Iron (Fe)</td>
<td>1000 micrograms</td>
</tr>
</tbody>
</table>

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

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

Use in children
SUPPLYELT® must not be used in children.

If you take too much SUPPLYELT® than you should
Your doctor will stop your treatment with SUPPLYELT® 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.

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:
e-mail: medsafety@hpra.ie
Tel: +353 1 6764971 Fax: +353 1 6762517
IRL - Dublin 2
HPRA Pharmacovigilance

Ireland

5. How to store SUPPLYELT®
After dilution, distribution 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.

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

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) 1900 micrograms (as Ferrous gluconate)
The other ingredients are hydrochloric acid and water for injections.
What SUPPLYELT® looks like and contents of the pack
SUPPLYELT® is a clear, uncloudy 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
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Manufacturer
Laboratoire AGUETTANT
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Distributed by
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