B. PACKAGE LEAFLET

Package leaflet: Information for the user

JUNYELT, Concentrate for solution for infusion
(For preterm, and term newborns, infants and children)

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 JUNYELT, Concentrate for solution for infusion, but will be referred as JUNYELT throughout the whole leaflet.

What is in this leaflet

1. What JUNYELT is and what it is used for

JUNYELT is a concentrate for solution for infusion, especially designed for preterm and term newborns, infants and children.

It contains five trace elements (zinc, copper, manganese, iodine, selenium), which are considered as essential because the body cannot produce them but needs them in very small quantities in order to function properly. Trace elements are normally provided by a balanced diet.

JUNYELT is used to provide trace elements to preterm and term newborns, infants and children who cannot eat normally and need intravenous (into a vein) feeding.

2. What you need to know before you use JUNYELT

Your child should not receive JUNYELT:
- if he/she is allergic (hypersensitive) to any of the ingredients of JUNYELT (See section 6 of this leaflet).
- if he/she suffers from Wilson's disease (an inherited disorder where there is excessive amount of copper in the body).
- if he/she has abnormally high level of any of the ingredients of the product in his/her blood. (If you have any doubt, ask your doctor).

Warnings and precautions
Talk to your doctor before using JUNYELT if your child:
• has got any liver or kidney problems.
• has got any thyroid gland problems.

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

Other medicines and JUNYELT
Tell your doctor if your child is taking, has recently taken or might take any other medicines, including medicines obtained without a prescription.

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

3. How to use JUNYELT

JUNYELT will be given to your child intravenously (into a vein) by infusion (IV drip) by a nurse or doctor. They will decide on the correct dose for him/her to receive.

Dosage

Preterm, and term newborns, infants and children (weighing 20 kg or less):
Basal requirements of the included trace elements are covered by 1 mL of JUNYELT per kg body weight per day to a maximum daily dose of 20 ml.

Children (weighing more than 20 kg):
A daily dose of 20 ml JUNYELT should meet basal trace element requirements.

JUNYELT should be supplemented with a single zinc injectable solution in case of administration to preterm infants to reach a total zinc parenteral intake of 450-500 µg/kg/day.

A daily iron infusion is recommended when preterm infants are receiving long term parenteral nutrition (> 3 weeks), and molybdenum add-on in case of parenteral nutrition > 4 weeks.

JUNYELT should not be administered directly to a patient but must be diluted before use.

If your child receives more JUNYELT than he/she should
It is very unlikely that your child will receive more infusion than he/she should as the doctor or nurse will monitor him/her during the treatment. However, if you think that your child has received too much JUNYELT, inform the doctor or nurse immediately.
Your doctor will stop the treatment with JUNYELT and do the necessary laboratory tests in the case of suspected overdose.

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

4. Possible side effects

Like all medicines, JUNYELT 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.

Reporting of side effects
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:
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store JUNYELT

After dilution, chemical and physical in-use stability has been demonstrated for 48 h at 25°C.
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 of 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.

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 JUNYELT contains
The active substances are:
For 10 ml JUNYELT (1 ampoule)

Zinc (Zn)	1000 µg	(as Zinc gluconate)
Copper (Cu)	200 µg	(as Copper gluconate)
Manganese (Mn)	5 µg	(as Manganese gluconate)
Iodine (I)	10 µg	(as Potassium iodide)
Selenium (Se)	20 µg	(as Sodium selenite)

The other ingredients are hydrochloric acid and water for injections.

What JUNYELT looks like and contents of the pack
JUNYELT is a clear, colourless concentrate for solution for infusion in a 10 ml ampoule.
JUNYELT is packed in boxes of 10 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
France

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The following information is intended for healthcare professionals only:

Pharmaceutical particulars:

Density	1.0
pH	2.7 to 3.3
Osmolality	15 mosm/kg
Osmolarity	15 mosm/L

Incompatibilities:

JUNYELT must not be used as a vehicle for other drugs.
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.
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

Instructions for use and handling:

Before use, check that the concentrate for solution for infusion is homogeneous and that the ampoule is not damaged and is free of particles.
JUNYELT is not intended to be administered in its current presentation. JUNYELT must be diluted or mixed with gentle agitation during preparation under strict aseptic conditions, before infusion.
JUNYELT must be diluted with respect to the final appropriate osmolarity.
For example:

- 5 or 10 ml of JUNYELT can be diluted in at least 50 ml of Sodium Chloride 0.9 % solution for infusion or Glucose 5% solution for infusion,
- 10 or 20 ml of JUNYELT can be diluted in at least 100 ml of Sodium Chloride 0.9 % solution for infusion or Glucose 5% solution for infusion.
- For these dilutions, the pH results range approximately between 3.5 – 4.5.

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.

For information on dosage please see the section 3 of the leaflet.