

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE MEDICINAL PRODUCT

JUNYELT, Concentrate for solution for infusion

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition of JUNYELT expressed in quantities of salts per ampoule (10 ml) and per ml.

JUNYELT	Theoretical quantities of raw materials <b>expressed in anhydrous</b>	
	For 1 ampoule (µg/10 ml)	For 1 ml (µg)
Zinc gluconate	6970	697.0
Copper gluconate	1428	142.8
Manganese gluconate	40.52	4.052
Potassium iodide	13.08	1.308
Sodium selenite	43.81	4.381

### Content per ampoule of 10 ml

	JUNYELT Molar composition (µmol/10 ml)	JUNYELT Weight composition (µg/10 ml)
Zinc (Zn)	15.30	1000
Copper (Cu)	3.15	200
Manganese (Mn)	0.091	5
Iodine (I)	0.079	10
Selenium (Se)	0.253	20

### Content per ml

	JUNYELT Molar composition (µmol/ml)	JUNYELT Weight composition (µg/ml)
Zinc (Zn)	1.53	100
Copper (Cu)	0.315	20
Manganese (Mn)	0.0091	0.5
Iodine (I)	0.0079	1
Selenium (Se)	0.0253	2

Each ml of solution contains 1.16 µg equivalent to 0.0506 µmol of sodium.  
Each 10 ml ampoule contains 11.6 µg equivalent to 0.506 µmol of sodium.

Each ml of solution contains 0.31 µg equivalent to 0.008 µmol of potassium.  
Each 10 ml ampoule contains 3.1 µg equivalent to 0.08 µmol of potassium.

For a full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Concentrate for solution for infusion

Clear, colourless solution.

Density 1.0

pH 2.7 to 3.3

Osmolality 15 mosmol/kg

Osmolarity 15 mosmol/L

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

JUNYELT is used as part of the intravenous nutrition of preterm and term newborns, infants and children. It is intended to meet the basal requirements for trace elements.

#### 4.2 Posology and method of administration

##### Posology

##### **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.

##### Method of administration

Intravenous route:

JUNYELT is not intended to be administered in its current presentation. It should be diluted according to the final desired osmolarity.

For instructions on dose adjustments in specific patient groups, see section 4.4.

For incompatibilities and instructions for use see 6.2 and 6.6.

#### 4.3 Contraindications

- Patients with known hypersensitivity to one of the actives substances and to the excipients.
- In case of Wilson's disease and if serum concentrations of any of the trace elements contained in JUNYELT are elevated.

#### 4.4 Special warnings and precautions for use

The solution should be used after an accurate control of the patient clinical and biological parameters. In paediatrics, individual trace element requirements may vary based on factors such as age, weight, underlying disease state and duration of parenteral nutrition.

Blood manganese levels should be regularly monitored in case of prolonged artificial nutrition. A dose reduction may be necessary or infusion of JUNYELT should be stopped if manganese levels rise into the potentially toxic range (please refer to appropriate reference ranges). The occurrence of neurological signs must evoke the possibility of a manganese overdose.

Particular attention must be paid when the product is given to patients with reduced biliary excretion, since this could interfere with the biliary elimination of manganese, copper and zinc, leading to accumulation and overdose. Copper overdose must be considered in the presence of nausea, vomiting, gastralgia. In patients with hepatic impairments or mild cholestasis the posology should be adapted. Besides, in case of pronounced cholestasis blood copper levels and hepatobiliary parameters should be monitored.

JUNYELT should be used with caution in patients with impaired renal function, as excretion of some trace elements (selenium and zinc) may be significantly decreased, leading to accumulation and overdose. In patients with renal impairments, the posology should be adapted.

JUNYELT should be used with caution in patients with manifest hyperthyroidism.

In patients undergoing medium to long-term parenteral nutrition, there is an increased frequency of copper, zinc and selenium deficiency. In such circumstances, when necessary, the dosage should be adapted with the use of an extra supply of solutions, which contain only these individual components. Because of a risk of precipitation, drugs or electrolytes should not be added to JUNYELT before the later has been diluted. The compatibility profile of infusion solutions administered through the same line should be verified.

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

#### **4.5 Interaction with other medicinal products and other forms of interaction**

No interaction studies have been performed.

#### **4.6 Fertility, pregnancy and lactation**

Not relevant.

#### **4.7 Effects on ability to drive and use machines**

Not relevant.

#### **4.8 Undesirable effects**

The following adverse reaction(s) have been reported during post-marketing experience of trace element solutions. The frequency is not known (cannot be estimated from the available data).

System organ class (SOC)	MedDRA Preferred Term
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Pain at the application site

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

## **4.9 Overdose**

If overdose is suspected, treatment with JUNYELT should be withdrawn. Overdose should be confirmed by appropriate laboratory tests.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Electrolyte solutions  
ATC code: B05XA31

JUNYELT is a solution composed of five essential trace elements (zinc, copper, manganese, iodine, selenium).

Trace elements are normally derived from a balanced diet and are necessary to maintain the metabolic equilibrium.

During artificial nutrition, the supply of trace elements is necessary because a deficiency of any one of them can generate important metabolic and clinical disturbances.

The composition of JUNYELT is based on current international recommendations regarding the requirements for trace elements in infants and children.

### **5.2 Pharmacokinetic properties**

The trace elements in JUNYELT, infused in physiological amounts, should be used in the same way as elements absorbed from an oral diet.

The different stages of trace element metabolism can be broken down as follows:

- Blood transport by proteins: albumin (Mn, Cu, Zn, Se), ceruloplasmin (Cu), selenomethionine (Se) or by non-protein carriers (I).
- Storage involving specific proteins: thyroid hormones (I), selenoproteins (Se) or non-specific proteins: metallothioneins (Cu, Zn, Mn).
- Elimination: The cationic trace elements (Cu, Mn, Zn) are eliminated mainly through biliary excretion. The anionic trace element (I) and some oxygenated forms of minerals (Se) are primarily excreted in the urine.

### **5.3 Preclinical safety data**

Since trace element solutions for intravenous injection are well-known products that have been used for medical purposes for many decades, no preclinical studies have been specifically performed with JUNYELT. The safety evaluation is based mainly on clinical experience and documentation.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

- Hydrochloric acid (for pH adjustment)
- Water for injections

### **6.2 Incompatibilities**

- JUNYELT must not be used as a vehicle for other drugs.
- This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

### **6.3 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.

### **6.4 Special precautions for storage**

Do not freeze.

### **6.5 Nature and contents of container**

10 ml solution in polypropylene ampoule in pack sizes of 10 and 50.  
Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal**

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.

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

**7. MARKETING AUTHORISATION HOLDER**

Laboratoire AGUETTANT  
1 rue Alexander Fleming  
69007 LYON  
FRANCE

**8. MARKETING AUTHORISATION NUMBER(S)**

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

**10. DATE OF REVISION OF THE TEXT**