Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

DECAN concentrate for solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition per 1000 ml DECAN	
Ferrous gluconate	199.9 mg
Copper gluconate	85 mg
Manganese gluconate	40.5 mg
Zinc gluconate	1742 mg
Sodium fluoride	80 mg
Cobalt II gluconate	0.280 mg
Sodium iodide	0.045 mg
Sodium selenite	3.83 mg
Ammonium molybdate	1.08 mg
Chromic chloride	1.14 mg
Density	1.00
Osmolality	19 mOsmol/kg water
Osmolarity	17.6 mOsmol/liter

Content per bottle of 40 ml

	DECAN Molar composition/40 ml	DECAN Weight composition/40 ml
Fe	17.9 micromol	1.000 mg
Zn	153.0 micromol	10.00 mg
Cu	7.550 micromol	0.480 mg
Mn	3.640 micromol	0.200 mg
F	76.30 micromol	1.450 mg
Co	0.0250 micromol	1.470 microg
I	0.0120 micromol	1.520 microg
Se	0.8870 micromol	0.070 mg
Mo	0.2610 micromol	0.025 mg
Cr	0.2890 micromol	0.015 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for solution for infusion
Clear, limpid and slightly yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

DECAN is used as part of an intravenous nutrition regimen, to cover basal or moderate increased needs of trace elements in parenteral nutrition.

4.2 Posology and method of administration

For adults only.
The recommended daily dose in patients with basal to moderately increased requirements is one vial (40 ml) of DECAN.
In cases of significantly increased trace element requirements (such as extensive burns, severe hypercatabolic major trauma patients) 2 vials (80 ml) of DECAN may be given per day, and monitoring of serum trace elements values is recommended.
DECAN is not intended to be administered in its current presentation
DECAN can also be included as such in parenteral nutrition admixtures. In this case, special attention must be paid to the compatibility of both products.
For incompatibilities and instructions for use see 6.2 and 6.6.

4.3 Contraindications

Children or patients less than 40kg body weight
Pronounced cholestasis (serum bilirubin > 140µmol/l)
DECAN should not be administered:
- to patients with known hypersensitivity to the active substances and to the excipient.
- in cases of Wilson's disease and hemochromatosis, and if serum concentrations of any of the trace elements contained in DECAN are elevated

4.4 Special warnings and precautions for use

The solution should be used after an accurate control of the clinical and biological parameters. Manganese blood levels should be regularly monitored in case of prolonged artificial nutrition: dose reduction may be necessary or DECAN infusion should be stopped if manganese levels rise into the potentially toxic range (please refer to appropriate reference ranges).

Particular attention should be reserved when the product is given to patients with reduced biliary excretion, since it could interfere with the biliary elimination of manganese, copper and zinc, leading to accumulation and overdose.
DECAN should be used with caution in patients with impaired renal function as excretion of some trace elements (selenium, fluoride, chromium, molybdenum and zinc) may be significantly decreased.
In patients with renal, hepatic impairments or mild cholestasis the posology should be adapted.

In patients undergoing medium to long term parenteral nutrition, there is an increased frequency of iron, zinc and selenium deficiency. Due to the very low content of iodine, iodine deficiency can occur in the absence of other supply such as iodine containing antibacterial skin solutions. 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.
For patients receiving repeated blood transfusions, a risk of iron overload can be observed.

This product contains 0.078 mmol of sodium (1.796 mg) per dose, i.e essentially "sodium free".

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, pregnancy and lactation

No safety data for DECAN are available when it is administered during pregnancy and lactation. Therefore, DECAN should not be used during pregnancy and lactation except after special consideration and if it is absolutely necessary.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

The following adverse reaction(s) have been reported spontaneously during Post-Marketing use of the product. The frequency cannot be estimated due to the nature of the data.

System organ class (SOC)	MedDRA Preferred Term
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Application site pain

4.9 Overdose

Overdose with DECAN is extremely unlikely since the quantity of trace elements per vial is well below known toxic levels. Anaphylactic reactions have been observed in some cases when iron was given intravenously. If overdose is suspected, treatment with DECAN should be withdrawn. Overdose would be confirmed by appropriate laboratory tests.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Solution of trace elements for infusion - B05XA31
DECAN is a balanced solution composed of the ten essential trace elements, which are necessary to maintain the metabolic equilibrium.
Trace elements are normally derived from a balanced diet, but the need increases in case of hypercatabolism (surgery, major trauma, burns), insufficient supply or abnormal loss and in cases of poor absorption (short bowel disease or Crohn's disease).
The composition of DECAN is based on present international recommendations concerning the requirements for trace elements:

	DECAN (1 - 2 vials)	Recommended* Intravenous Daily Intakes
Fe (mg)	1 - 2	1.2
Zn (mg)	10 - 20	2.4 - 15
Cu (mg)	0.48 - 0.96	0.3 - 1.6
Mn (mg)	0.2 - 0.4	0.15 - 0.8
F (mg)	1.45 - 2.90	0.95
Co (microg)	1.47 - 2.94	-
I (microg)	1.52 - 3.04	131
Se (microg)	70 - 140	30 - 500
Mo (microg)	25 - 50	19 - 200
Cr (microg)	15 - 30	10 - 30

* according to American Medical Association 1979, 1984; Fleming 1989; Berger 1995; Shenkin 1995.
During an artificial nutrition, a supply of trace elements is necessary since a deficiency of one of them can generate important metabolic and clinical disturbances.

5.2 Pharmacokinetic properties

The various pathways of trace element metabolism can be summarised as follows :

- Blood transport by proteins: albumin (Mn, Cu, Zn, Se), transferrin (Fe, Cr), ceruloplasmin (Cu), cyanocobalamin (Co), selenomethionine (Se), or non protein carriers (F, I, Mo).
- Storage involves specific proteins: ferritin (Fe), thyroid hormones (I), cobalamins (Co), selenoproteins (Se), or non specific proteins: metallothioneins (Cu, Zn, Mn, Mo) or fluoroapatite (F).
- Elimination:

The cationic trace elements (Fe, Cu, Mn, Zn) are eliminated mainly through biliary excretion.
The anionic trace elements (I, F) and some oxygenated forms of minerals (such as Mo, Co, Se, Cr) are primarily excreted in the urine.
Elimination through the lungs and the skin is possible.

5.3 Preclinical safety data

Preclinical data based on conventional studies of safety pharmacology, repeated dose toxicity, toxicity to reproduction, genotoxicity and carcinogenicity for trace elements in DECAN are incomplete. Since DECAN is intended for replacement therapy, the risk for toxic effects is considered to be low at normal clinical use.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Glucono delta-lactone
- Water for Injections

6.2 Incompatibilities

- DECAN must not be used as a vehicle for other drugs.
- DECAN, as with other trace element solutions, cannot be added directly to inorganic phosphate (additive) solutions.
- Degradation of ascorbic acid in parenteral nutrition admixtures is accelerated by trace elements

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf life

2 years.
After dilution, chemical and physical in-use stability has been demonstrated for 24 h at 25°C.
From a microbiological point of view, the product should be used immediately after dilution or addition. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 h at 5°C unless dilution or addition has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Do not store above 25°C, do not freeze
Keep the container in the outer carton in order to protect from light.

6.5 Nature and contents of container

Glass bottle of 50 ml (colourless/transparent glass type II) filled with 40 ml;

Package size: 40ml x 1 unit
40ml x 25 units

6.6 Special precautions for disposal and other handling

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

- 40ml of DECAN can be diluted in at least 250ml of Sodium Chloride 0.9 % solution for infusion,
- 40 ml of DECAN can be diluted in at least 500 ml of Glucose 5% to 70% solutions for infusion. In case of dilution of Decan in Glucose solutions above 20%, the dilution must not be administered alone with regard to the final osmolarity.

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.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 167/102/1

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