SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Vamin 14 solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

A 1000ml solution for infusion contains:

Alanine	12.0	g
Arginine	8.4	g
Aspartic Acid	2.5	g
L-Cysteine/Cystine (as Hydrochloride)	420	mg
Glutamic Acid	4.2	g
Glycine	5.9	g
L-Histidine	5.1	g
Isoleucine	4.2	g
Leucine	5.9	g
L-Lysine (as Hydrochloride)	6.8	g
L-Methionine	4.2	g
Phenylalanine	5.9	g
Proline	5.1	g
Serine	3.4	g
L-Threonine	4.2	g
L-Tryptophan	1.4	g
L-Tyrosine	170	mg
Valine	5.5	g
Sodium	100	mmol
Potassium	50	mmol
Calcium	5	mmol
Magnesium	8	mmol
Chloride	100	mmol
Sulphate	8	mmol
Acetate	135	mmol

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for infusion
Clear, colourless to straw coloured solution of L-amino acids with electrolytes.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the prophylactic or therapeutic treatment of protein depletion, where sufficient enteral feeding is impossible or impracticable.

4.2 Posology and method of administration

Posology

Adults
Depending upon patient requirements up to one litre intravenously per 24 hours. Vamin 14 is administered by slow intravenous infusion at approximately 40 drops per minute or slower corresponding to an infusion time of at least eight hours per litre.

Elderly
Age per se requires no adjustment of the adult dosage. However, caution should be exercised in the "frail" elderly, and indeed in all patients with poor renal, cardiac or liver function, where smaller volumes should be used depending on the individual patients' requirements and condition.

Paediatric Population

Infants
Can be administered at the physician's discretion. An amino acid solution containing larger amounts of cysteine/cystine and tyrosine may be considered more appropriate in infants.

Method of administration
For intravenous use only.
When used in children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see section 4.4, 6.3 and 6.6).

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
Vamin 14 is contraindicated in patients with irreversible liver damage and in severe uraemia when dialysis facilities are not available.

4.4 Special warnings and precautions for use

- Care must be exercised in the administration of large volume infusion fluids to patients with cardiac insufficiency.

- Amino acid infusions must also be administered with caution to patients with disturbances in protein metabolism.

- Hyperkalaemia, hypernatraemia and acidosis should be corrected prior to commencement of intravenous nutrition; serum electrolytes, blood glucose levels, acid-base balance, and fluid levels should be regularly monitored.

- Vamin 14 should be given with caution to patients with electrolyte retention e.g. impaired renal function and to those with cardiac disease requiring electrolyte restriction or drug therapy e.g. digitalis.

- Potassium replacement should be carefully controlled, as plasma potassium levels may not be directly related to tissue levels.

- Light exposure of solutions for intravenous parenteral nutrition, especially after admixture with trace elements and/or vitamins, may have adverse effects on clinical outcome in neonates, due to generation of peroxides and other degradation products. When used in children below 2 years, Vamin 14 should be protected from ambient light until administration is completed (see section 4.2, 6.3 and 6.6).

4.5 Interaction with other medicinal products and other forms of interaction

Amino acid solutions may precipitate acute folate deficiency and folic acid should be given daily.

4.6 Fertility, pregnancy and lactation

Animal reproduction studies have not been carried out with Vamin 14. However, there are published reports on the successful and safe infusion of amino acid solutions during pregnancy in the human.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Vomiting, flushing and sweating may occur, rarely, particularly if the recommended rate of infusion is exceeded. Abnormal liver function tests have been observed during intravenous infusion, but these return to normal when artificial feeding is stopped.

Cholestasis has been reported in some patients receiving intravenous nutrition.

Thrombophlebitis may occur when peripheral veins are used but the incidence is reduced by the simultaneous infusion of fat emulsion.

Reporting of suspected adverse reactions
Reporting of 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 Yellow Card scheme at www.mhra.gov.uk/yellowcard.

4.9 Overdose

(In general, significant overdosage with Vamin 14 does not occur). Excessive infusion rates may result in nausea, vomiting, flushing and sweating.

The effects of overdosage are likely to be due to the volume infused and the hypertonicity of the solution, i.e. circulating overload. The amount required to produce this effect will vary depending on the patients' condition, cardiac and renal status.

There are no specific antidotes for overdosage.

In case of suspicion of overdosage the infusion should immediately be stopped.

Emergency procedure should be general supportive measures: respiratory and cardiovascular. Close biochemical monitoring would be essential and specific abnormalities treated appropriately, perhaps by the careful infusion of hypotonic solutions and concomitant diuretic therapy, and administration of sodium bicarbonate for metabolic acidosis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Vamin 14 is formulated to supply amino acids in the physiological L-form with electrolytes for intravenous nutrition.

5.2 Pharmacokinetic properties

Vamin 14 is an amino acid solution without interest for pharmacokinetic studies.

5.3 Preclinical safety data

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glacial Acetic Acid
Water for Injections

6.2 Incompatibilities

Additives may only be added to Vamin 14 where compatibility is known.

6.3 Shelf life

24 months.

When used in children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see section 4.2, 4.4 and 6.6).

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Light weight glass bottle (Ph. Eur. Type II) with butyl rubber stopper, 31mm (FM 157) containing 500 or 1000 ml of solution.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

When used in children below 2 years, protect from light exposure, until administration is completed. Exposure of Vamin 14 to ambient light, especially after admixture with trace elements and/ or vitamins, generates peroxides and other degradation products that can be reduced by protection from light exposure (see section 4.2, 4.4 and 6.3).

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 08828/0118

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Date of latest renewal: March 2009

10 DATE OF REVISION OF THE TEXT

27/01/2020