FINAL PACKAGE INSERT [1]

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

VAMIN 18 ELECTROLYTE FREE intravenous solution

COMPOSITION

Each 1 000 ml contains:

L-alanine .....16,0 g

Glycine .....7,9 g

L-arginine .....11,3 g

L-aspartic acid. .....3,4 g

L-cysteine/L-cystine .....560 mg

L-glutamic acid . .....5,6 g

L-histidine .....6,8 g

L-isoleucine .....5,6 g

L-leucine . .....7,9 g

L-lysine acetate 12,7 g, equivalent to L-lysine .....9,0 g

L-methionine .....5,6 g

L-phenylalanine .....7,9 g

L-proline .....6,8 g

[1] Regulation 9 compliant notification only

L-serine .....4,5 g

L-threonine .....5,6 g

L-tryptophan .....1,9 g

L-tyrosine .....230 mg

L-valine . .....7,3 g

Glacial acetic acid to pH 5,6

Water for injection to 1 000 ml

One litre contains 51,6 g of essential amino acids (114 g total amino acids) corresponding to 18,0 g nitrogen.

Energy content 1,9 MJ (460 kcal).

The solution is free from sugar, antioxidants and preservatives.

PHARMACOLOGICAL CLASSIFICATION

A 25.2 Other nutrients.

PHARMACOLOGICAL ACTION

VAMIN 18 ELECTROLYTE FREE intravenous solution is a concentrated solution of amino acids. The solution contains all 18 amino acids needed for protein synthesis.

INDICATIONS

For intravenous supply of amino acids especially to patients with highly increased requirements who are unable to receive sufficient amounts of protein enterally.

CONTRAINDICATIONS

Uraemia when dialysis facilities are not available. Impairment of liver function. Renal failure. Hypersensitivity to one or more amino acids. In patients with inborn errors of amino acid metabolism.

WARNINGS AND SPECIAL PRECAUTIONS

The solution is hypertonic and thrombophlebitis may occur when the solution is infused into peripheral veins.

INTERACTIONS

Not to be expected.

PREGNANCY AND LACTATION

The risk/benefit relationship should be considered before administering VAMIN 18 ELECTROLYTE FREE during pregnancy or lactation.

DOSAGE AND DIRECTIONS FOR USE

Up to 1 litre intravenously per day depending upon the patient's requirement.

VAMIN 18 ELECTROLYTE FREE should be infused slowly, at a rate not exceeding 1 litre in 8 hours.

When VAMIN 18 ELECTROLYTE FREE intravenous solution is infused simultaneously with 500 ml INTRALIPID® 20% over 8 hours the drip rate should be adjusted to about 40 drops/minute of the amino acid solution and to about 20 drops/minute of INTRALIPID.

The following electrolytes can be added to 1 000 ml VAMIN 18 ELECTROLYTE FREE intravenous solution without risk of precipitation: 480 mmol Na+ and 480 mmol K^+ as chlorides, 24 mmol Ca^{2+} as glubionate and 48 mmol Mg^{2+} as sulphate.

The contents of the bottle are for a single infusion only. Any remaining solution must be discarded.

Use only additives of known compatibility. Do not use if bottle is leaking or if solution is cloudy or contains a precipitate.

SIDE EFFECTS

Gastrointestinal disorders:

Frequency unknown: Nausea, vomiting (which may occur when the infusion rate is high).

Renal and urinary disorders:

Frequency unknown: Intravenous infusion of VAMIN 18 ELECTROLYTE FREE is accompanied by increased urinary excretion of the trace elements copper and, in particular, zinc, which should be taken into account in the dosing of trace elements, particularly during long-term intravenous nutrition.

Vascular disorders:

Frequent: Thrombophlebitis

Hepato-biliary disorders:

Frequency unknown: Transient increases in liver tests.

General disorders:

Frequency unknown: Flushing and sweating may occur when the infusion rate is high.

Immune system disorders:

Hypersensitivity reactions have been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See SIDE-EFFECTS. Treatment is supportive and symptomatic.

IDENTIFICATION

Clear, colourless to slightly yellow solution of amino acids.

PRESENTATION

Glass bottles of 500 ml and 1 000 ml.

Not all pack sizes may be marketed.

STORAGE INSTRUCTIONS

Store below 25 °C. Keep out of reach of children.

REGISTRATION NUMBER

S/25.2/98

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Fresenius Kabi South Africa (Pty) Ltd

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DATE OF PUBLICATION OF THIS PACKAGE INSERT

Date of registration: 17 December 1985

Date of last approval: 07 April 2006

Date of Regulation 9 implementation: 27 May 2016