IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0566/024/002
Case No: 2054816

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Fresenius Kabi Limited

Cestrian Court, **Eastgate Way**, **Manor Park, Runcorn**, **Cheshire WA7 1NT**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Vamin 18 Electrolyte - Free Solution for Infusion, 1000ml.

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **10/03/2009** until **20/06/2009**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vamin 18 Electrolyte-Free Solution for Infusion.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1000 ml contains:

Alanine	16.0	g
Arginine	11.3	g
Aspartic acid	3.4	g
Cysteine/cystine	560.0	mg
Glutamic acid	5.6	g
Glycine	7.9	g
Histidine	6.8	g
Isoleucine	5.6	g
Leucine	7.9	g
Lysine	9.0	g
Methionine	5.6	g
Phenylalanine	7.9	g
Proline	6.8	g
Serine	4.5	g
Threonine	5.6	g
Tryptophan	1.9	g
Tyrosine	230.0	mg
Valine	7.3	g

Product Particulars

Nitrogen content	18.0	g/l	
Energy content	460.0	kcal	(1.9 mJ/l)
Osmolality	1130.0	mosm/kg water	
pH	5.6		

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.

A clear, colourless to slightly yellow solution of amino acids.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the prophylaxis or therapeutic treatment of protein depletion, where sufficient enteral nutrition is impossible or impracticable. It is particularly suited to meetmoderately increased requirements for nitrogen in patients in whom fluid intake is a limiting factor.

4.2 Posology and method of administration

Route of administration
Intravenous.

Adults
Depending upon patient requirements up to 1 litre intravenously in 24 hours. Administration should be by slow intravenous infusion at a rate not exceeding 2 ml per minute, corresponding to approximately 40 drops per minute or an infusion time of at least 8 hours/litre.

Infants
May be administered at physicians discretion, but a solution containing larger amounts of cysteine/cystine and tyrosine and lower amounts of phenylalanine may be considered more appropriate in infants.

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

4.3 Contraindications

Advanced liver or renal disease where dialysis facilities are not available.

4.4 Special warnings and precautions for use

Where shock, metabolic acidosis or severe dehydration is present, the condition should be corrected before the commencement of intravenous feeding.

Central venous catheters for parenteral feeding should be placed using strict confirmation where possible. Asepsis should be maintained during changes of tubing and dressing and use of the catheter should be confined to IV feeding alone.

Patients receiving these infusions may suffer from air embolism, central venousthrombosis, catheter-linked sepsis, and infusion thrombo-phlebitis. Immuno-suppressed patients are particularly prone to infections.

Abnormalities of liver function tests and cholestasis have been observed in patients including infants receiving total parenteral nutrition.

To achieve optimal utilization of administered amino acids, adequate energy sources e.g. glucose solution and fat emulsion, should be provided.

Care should be exercised in the administration of large volume infusion fluids to patients with cardiac insufficiency, similarly caution should be taken with the administration of amino acid infusions to patients with disturbances in protein metabolism.

Serum electrolytes, acid-base balance and fluid balance should be regularly monitored.

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 Pregnancy and lactation

Animal reproduction studies have not been carried out with Vamin 18 Electrolyte-Free. There are, however, 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 applicable.

4.8 Undesirable effects

Vomiting, flushing and sweating may occur if the recommended rate of infusion is exceeded.

4.9 Overdose

In general significant overdosage with Vamin 18 Electrolyte-Free 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 patient's 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 procedures 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. Expert advice should be sought.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Vamin 18 Electrolyte-Free is formulated to supply amino acids in the physiological L- form for intravenous nutrition.

5.2 Pharmacokinetic properties

Vamin 18 Electrolyte-Free is an amino acid solution without interest for pharmacokinetic studies.

5.3 Preclinical safety data

No further preclinical safety data are available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acetic acid glacial
Water for Injections

6.2 Incompatibilities

Additives may only be added to Vamin 18 Electrolyte-Free where compatibility is known.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25^{o}C. Do not freeze.

6.5 Nature and contents of container

Type II (Ph. Eur.) glass infusion bottles with butyl rubber stoppers and outer aluminium cap.

Pack sizes: 1000ml.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Do not use if the bottle is leaking or if the solution is cloudy or contains a precipitate.

Discard any unused contents.

7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Limited
Cestrian Court
Eastgate Way
Runcorn
Cheshire
WA7 1NT
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 0566/024/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 21st June 1984

Date of last renewal: 21st June 2004

10 DATE OF REVISION OF THE TEXT

May 2006