IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0167/091/004
Case No: 2036975

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

Baxter Healthcare Limited

Caxton Way, **Thetford**, **Norfolk IP24 3SE**, **United Kingdom**

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

Synthamin 14, 8.5% w/v Amino Acid Intravenous Infusion, Solution for Infusion

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 **03/12/2008**.

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

Synthamin 14, 8.5% w/v Amino Acid Intravenous Infusion, Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Leucine	6.20	g/l
Isoleucine	5.10	g/l
Lysine (as hydrochloride salt)	4.93	g/l
Valine	4.93	g/l
Phenylalanine	4.76	g/l
Histidine	4.08	g/l
Threonine	3.57	g/l
Methionine	3.40	g/l
Tryptophan	1.53	g/l
Alanine	17.60	g/l
Arginine	9.78	g/l
Glycine	8.76	g/l
Proline	5.78	g/l
Serine	4.25	g/l
Tyrosine	340.00	mg/l
Sodium Acetate	5.94	g/l
Dipotassium phosphate	5.22	g/l
Sodium Chloride	1.54	g/l
Magnesium Chloride hexahydrate	1.02	g/l

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Infusion
The product is a clear or slightly coloured sterile aqueous solution.
pH 5-7 Tonicity mOsm/l 1160

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Synthamin 14, 8.5% Amino Acid Intravenous Infusion is indicated for the correction of protein depletion and the maintenance of adequate nitrogen and electrolyte balance.

4.2 Posology and method of administration

The solution is for administration by intravenous infusion through a central venous catheter with the tip located in the central vena cava. The total daily dose of the solution depends upon the individuals protein requirements under the circumstances of his illness and of the degree of existing imbalance.

4.3 Contraindications

Synthamin 14, 8.5% Amino Acid Intravenous Infusion is contraindicated in patients with renal failure, severe liver disease and patients with a known hypersensitivity to one or more amino acids.

Use through infusion equipment through which blood has been, is being, or will be administered, because of potential pseudoagglutination.

4.4 Special warnings and precautions for use

Adequate intake of carbohydrate and essential fatty acids should be given concomitantly with administration of these preparations to ensure sufficient megajoules to permit optimum utilization of amino acids and avoid acidosis. A quantity not less than 0.75 megajoules (180 calories) per gram of nitrogen should be used.

Because of the hyperosmotic nature of the solution, it should be administered through an indwelling centrally placed venous catheter. Prolonged infusion may result in thrombophlebitis.

The quantities of electrolytes present may require supplementation in the presence of hypokalaemia or in patients with gastrointestinal suction, or drainage, fistula drainage or excessive tissue fluid loss as in burns.

Patients receiving these solutions should be under close surveillance with regular clinical and laboratory evaluation. Particular attention should be paid to the hazards of hyperammonaemia and hyperchloraemic acidosis.

These solutions should only be administered with extreme caution to patients with liver dysfunction or renal functional impairment.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent administration with highly concentrated dextrose solutions may result in the development of hyperglycaemia, glycosuria or hyperosmolar syndrome.

Check additive compatibility before use.

4.6 Pregnancy and lactation

The safety of the use of Synthamin 14, 8.5% Amino Acid Intravenous Infusion during pregnancy or lactation has not been established.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Synthamin 14, 8.5% Amino Acid Intravenous Infusion is hypertonic and liable to cause venous irritation at the site of injection.

4.9 Overdose

None stated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

None stated.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

No data is presented as amino acids and electrolytes are basic and widespread elements in mammalian metabolism and therefore conventional animal safety testing is not appropriate.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injection
Glacial Acetic Acid (for pH adjustment)

6.2 Incompatibilities

Synthamin 14, 8.5% Amino Acid Intravenous infusion should not be administered simultaneously with, before or after an administration of blood through the same infusion equipment, because of the possibility of pseudoagglutination.

Do not add any other medication or substance to this solution unless compatibility is known.

6.3 Shelf Life

Unopened: 2 years
Opened: use immediately, discard any unused portion.

6.4 Special precautions for storage

Do not store above 25^{o}C. Product shall be protected from light and oxygen by being kept in the aluminium overpouch until required for use. Once removed from the over pouch, the product should be used immediately.

6.5 Nature and contents of container

The products are supplied in poly (vinyl chloride) plastic Viaflex® containers which are sealed in a plastic laminated overpouch.

The solution is supplied in 250 ml, 500 ml and 1000 ml fill volumes.

Not all pack sizes may be marketed.

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 administer unless solution is clear and the container is undamaged.

Do not store partly used containers.

Discard all equipment after use.

Do not administer blood through the same giving set.

Do not add any other medication or substance to this solution unless compatibility is known.

Once removed from the overpouch, the product should be used immediately.

7 MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd.
Caxton Way
Thetford
Norfolk IP24 3SE
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 167/91/4

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 March 1987

Date of last renewal: 13 March 2007

10 DATE OF REVISION OF THE TEXT

November 2008