IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0167/092/004
Case No: 2030304

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 without Electrolytes, 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 **02/10/2007**.

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 without Electrolytes, 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

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 5.0-7.0 Tonicity mOsm/l 880

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Synthamin Intravenous Infusions provide a biologically available source of Nitrogen (L-Amino Acids) for protein synthesis. When administered with an adequate source of energy such as carbohydrate solutions, minerals and vitamins the mixture provides (with the exception of fatty acids) sufficient parenteral nutrition for patients unable to absorb adequate nutrition via the enteral route.

4.2 Posology and method of administration

This solution may be administered by continuous infusion through a central venous catheter, with the tip located in the Vena Cava. The total daily dose of the solution depends upon the individual’s protein requirements under the circumstances of their illness and the degree of existing imbalance.
Recommended daily allowances of protein range from 2.2g/kg bodyweight for infants, to 56g per day for a 70kg adult. However, larger doses may be administered in cases of trauma or marked malnutrition. An associated source of non-protein energy should be administered in a quantity not less than 0.75MJ (180kcal) per gram nitrogen administered.

4.3 Contraindications

Synthamin Intravenous Infusions without Electrolytes are contraindicated in patients with renal failure, severe liver disease, or known hypersensitivity to one or more amino acids.

4.4 Special warnings and precautions for use

Synthamin Intravenous Infusions are hyperosmotic and may cause venous irritation.
Frequent clinical evaluations and laboratory tests are necessary during administration. Studies should include blood sugar, serum proteins, kidney and liver function tests, electrolytes, haemogram, Carbon Dioxide combining power or content, serum and urine osmolarities, blood cultures and blood ammonia levels.
Administration of Synthamin solutions to patients with hepatic insufficiency may lead to imbalances in amino acid metabolism or hyperammonaemia. Blood ammonia levels should be monitored and administration adjusted or halted as necessary.
Mixtures containing amino acids may precipitate folate deficiency and folic acid should be administered daily.
It is essential to provide an adequate source of non-protein energy concurrently if parenterally administered amino acids are to be retained and utilised by the body. Concentrated glucose solutions are an effective source of such energy.
The infusion of Synthamin solutions in combination with high concentration Glucose solutions may cause hyperglycaemia, glycosuria, and hyperosmolar Syndrome. Blood and urine glucose should be monitored on a routine basis.
Care should be taken to avoid circulatory overload, particularly in patients with cardiac insufficiency.

4.5 Interaction with other medicinal products and other forms of interaction

The solution should not be administered at the same time as, before, or after an administration of blood through the same infusion equipment, because of the possibility of pseudoagglutination.
Check additive compatibility before use.

4.6 Pregnancy and lactation

The safety of the use of Synthamin 14, 8.5% Amino Acid Intravenous Infusion without Electrolytes 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

If adverse reaction occurs, discontinue use.

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 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 Injections
Sodium Acetate (for pH adjustment)
Glacial Acetic Acid (for pH adjustment)

6.2 Incompatibilities

Synthamin 14, 8.5% Amino Acid Intravenous Infusion with Electrolytes 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°C. Product shall be protected from light and oxygen by being kept in the aluminium overpouch until required for use. Once removed from the overpouch, 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 Limited
Caxton Way
Thetford
Norfolk IP24 3SE
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 167/92/4

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 02 October 1987

Date of last renewal: 02 October 2007

10 DATE OF REVISION OF THE TEXT

November 2008