# 1 SYNTHAMIN (infusion, solution)

**Synthamin 9** (amino acid) with electrolytes, 5.5% Infusion, solution
**Synthamin 13** (amino acid) with electrolytes, 8% Infusion, solution
**Synthamin 17** (amino acid) with electrolytes, 10% Infusion solution

**Synthamin 9** (amino acid) (without electrolytes), 5.5% Infusion, solution
**Synthamin 13** (amino acid) (without electrolytes), 8% Infusion, solution
**Synthamin 17** (amino acid) (without electrolytes), 10% Infusion, solution

# 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

**Synthamin** intravenous infusion solutions are solutions of essential and non-essential L-amino acids provided with or without electrolytes, available in 5.5%, 8% and 10% strengths.. Each strength has a pH of approximately 6.0 and each 500mL unit contains amino acids and nitrogen the following quantities:

*Amino acids and nitrogen:*

| | 5.5% | 8% | 10% |
|---|---|---|---|
| Amino Acids | 27.5g | 40g | 50g |
| Nitrogen | 4.5g | 6.6g | 8.3g |

*Each 1000mL of Synthamin infusion solutions without electrolytes contains:*

| | 5.5% | 8% | 10% |
|---|---|---|---|
| L-Amino Acids | 55g | 80g | 100g |
| Total Nitrogen | 9.09g | 13.2g | 16.5g |
| Approximate pH | 6.0 | 6.0 | 6.0 |
| Protein Equivalents | 56.8g | 82.7g | 103.0g |

*Essential amino acids*

| | 5.5% | 8% | 10% |
|---|---|---|---|
| Leucine | 4.02g | 5.84g | 7.30g |
| Phenylalanine | 3.08g | 4.48g | 5.60g |
| Methionine | 2.20g | 3.20g | 4.00g |
| Lysine (as the hydrochloride salt) | 3.19g | 4.64g | 5.80g |
| Isoleucine | 3.30g | 4.80g | 6.00g |
| Valine | 3.19g | 4.64g | 5.80g |
| Histidine | 2.64g | 3.84g | 4.80g |
| Threonine | 2.31g | 3.36g | 4.20g |
| Tryptophan | 999mg | 1.44g | 1.80g |

*Nonessential amino acids*

| | 5.5% | 8% | 10% |
|---|---|---|---|
| Alanine | 11.4g | 16.6g | 20.7g |
| Glycine | 5.66g | 8.24g | 10.3g |
| Arginine | 6.32g | 9.20g | 11.5g |
| Proline | 3.74g | 5.44g | 6.80g |
| Tyrosine | 220mg | 320mg | 400mg |
| Serine | 2.75g | 4.00g | 5.00g |
| Approximately 1.5mmol/L sodium metabisulfite B.P. is added as stabiliser. | | | |

*In addition to the above, Synthamin infusion solutions with electrolytes contain in each 1000mL:*

*Electrolytes*

| | 5.5% | 8% | 10% |
|---|---|---|---|
| Sodium Acetate, B.P. | 4.31g | 6.8g | 6.8g |
| Dibasic Potassium Phosphate | 5.22g | 5.22g | 5.22g |
| Sodium Chloride, B.P | 2.24g | 1.17g | 1.17g |
| Magnesium Chloride, B.P | 1.02g | 1.02g | 1.02g |

*Synthamin infusion solutions with electrolytes contain the following non-nitrogenous ionic profile:*

*Ions*

| | Millimoles/litre | | |
|---|---|---|---|
| | 5.5% | 8% | 10% |
| Sodium | 73 | 73 | 73 |
| Potassium | 60 | 60 | 60 |
| Magnesium | 5 | 5 | 5 |
| Acetate* | 100 | 130 | 150 |
| Chloride | 70 | 62 | 70 |
| Phosphate (as $HPO_4^{2-}$) | 30 | 30 | 30 |
| * Acetate is added as sodium acetate and as acetic acid used for pH adjustment. | | | |

*Synthamin infusion solutions without electrolytes contain the following anion profile:*

*Ions*

| | Millimoles/litre | | |
|---|---|---|---|
| | 5.5% | 8% | 10% |
| Acetate* | 45 | 66 | 82 |
| Chloride+ | 22 | 32 | 40 |
| * Derived from pH adjustment with acetic acid<br>+ Contributed by the Lysine Hydrochloride | | | |

| Hypertonic | Approx. milliosmoles/litre |
|---|---|
| **Synthamin 9** (5.5%) Intravenous Infusion with Electrolytes | 820 |
| **Synthamin 9** (5.5%) Intravenous Infusion without Electrolytes | 550 |
| **Synthamin 13** (8%) Intravenous Infusion with Electrolytes | 1060 |
| **Synthamin 13** (8%) Intravenous Infusion without Electrolytes | 800 |
| **Synthamin 17** (10%) Intravenous Infusion with Electrolytes | 1260 |
| **Synthamin 17** (10%) Intravenous Infusion without Electrolytes | 1000 |

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Infusion, solution, in 500mL glass bottle.

**Synthamin** is to be administered via intravenous infusion.

**Synthamin** infusion solutions are sterile, nonpyrogenic, hypertonic, clear and colourless to slightly yellow solutions of essential and non-essential L-amino acids provided with or without electrolytes.

# 4 CLINICAL PARTICULARS

## 4.1 Therapeutic indications

Synthamin infusion solutions are indicated as an adjunct in the prevention of net nitrogen loss or in the treatment of negative nitrogen balance in patients where:

- the alimentary tract, by the oral, gastrostomy or jejunostomy route, cannot or should not be used,
- gastrointestinal absorption of protein is impaired, or
- metabolic requirements for protein are substantially increased, as with extensive burns.

## 4.2 Dose and method of administration

Parenteral medicinal products should be inspected visually for particulate matter and discoloration prior to administration. Use of a final filter is recommended during administration of all parenteral nutrition solutions.

*Dose*

The total daily dose of the solution depends on the patient's metabolic requirement and clinical response. The determination of nitrogen balance and accurate daily body weights corrected for fluid balance, are probably the best means of assessing individual nitrogen requirements. As indicated on an individual basis, vitamins and trace elements and other components (including glucose and lipids) can be added to the parenteral nutrition regimen to meet nutrient needs and prevent deficiencies and complications from developing (see section 4.4).

Fat emulsion co-administration should be considered when prolonged parenteral nutrition is required in order to prevent essential fatty acid deficiency (EFAD).

In adults, hypertonic mixtures of amino acids and glucose may be safely administered by continuous infusion through a central venous catheter with the tip located in the vena cava. Typically, 500mL of Synthamin infusion solution mixed with 500mL of 50% Glucose infusion with electrolytes (if indicated) is administered over an 8-hour period (if the rate of administration should fall behind schedule, no attempt to "catch up" to planned intake should be made). The osmolarity of a specific infusion solution must be taken into account when peripheral administration is considered.

The clinical needs of the patient may necessitate additional electrolyte supplementation despite the use of Synthamin infusion solution with electrolytes.

In addition to meeting nitrogen needs, the administration rate is governed, especially during the first few days of therapy, by the patient's tolerance to glucose. Daily intake of amino acids and glucose should be increased gradually to the maximum required dose as indicated by frequent determinations of urine and blood sugar levels. The flow rate must be adjusted taking into account the dose being administered, the daily volume intake, and the duration of the infusion. The recommended infusion rate upper limit is 0.2g amino acids/kg body weight/hour.

Recommended daily dietary allowances[1] for protein range from 2.2g/kg body weight for infants to 0.8g/kg body weight for adults. Associated carbohydrate calories should be administered in a quantity not less than 167 kilojoules (40 kilocalories)/kg body weight/day. Maximal nitrogen utilisation with Synthamin infusion solutions is promoted by providing approximately 840 non-protein kJ (200kcal)/g of infused nitrogen.

[1]Food and Nutrition Board National Academy of Sciences - National Research Council (Revised 1974) U.S.A.

Intravenous lipid (fat) emulsions 10% or 20% should be administered as part of an intravenous total nutrition program via peripheral vein (if given alone) or central venous catheter. For adults 10% or 20% lipid emulsion injections can provide up to a maximum of 60% of the patient's daily energy requirements. The other 40% or more should be provided by carbohydrate and amino acids. Both the lipid emulsion dose and these high amino acid doses are upper limits.

Levels up to these amounts can be employed; however, lesser amounts are commonly used. For the initial treatment of trauma or protein-calorie malnutrition, higher doses of protein and carbohydrate will be necessary to promote adequate patient response to therapy. The severity of the illness being treated is the primary consideration in determining proper dose level.

Care should be exercised to ensure the maintenance of proper levels of serum potassium. There may be need for exogenous insulin in certain cases (see section 4.4).

When used in neonates, infants and children, the solution (in containers and administration sets) should be protected from light exposure after admixture through administration (see section 4.4).

Any unused portion of Synthamin infusion solution should be discarded and should not be used for subsequent admixing.

*Paediatric dosage and administration*

The dosage of parenteral nutrition solution should be individually tailored to the amino acid and caloric requirements of the patient. The following approximate nitrogen equivalent and caloric values can be used as a means of calculating dosage:

| | |
|---|---|
| 10% Amino Acid Intravenous Infusion | 500mL = 8.3g nitrogen |
| 8% Amino Acid Intravenous Infusion | 500mL = 6.6g nitrogen |
| 5.5% Amino Acid Intravenous Infusion | 500mL = 4.54g nitrogen |
| 50% Glucose Intravenous Infusion | 500mL = 3930kJ (940kcals) |

The hyperosmotic nature of these solutions commonly used for parenteral nutrition dictates that they be administered via an indwelling intravenous catheter, the tip of which lies in a part of the blood stream with a high flow in order that immediate dilution takes place. Careful attention must be given to the proper care of the intravenous catheter to avoid contamination of the blood and consequent septicaemia. If fever develops, the solution, its delivery system and the site of the indwelling catheter should be changed. Strict aseptic technique must be used to prepare the amino acid-glucose mixture.

The use of a laminar flow hood is recommended. The solution so prepared is stable for up to 24 hours; any solution not administered immediately after preparation should be stored in a refrigerator for not longer than 24 hours.

Dosage for the paediatric patient usually will be higher than for adults in recognition of requirements of growth as well as of maintenance for neonates especially low birth weights and preterm neonates. Quantities of 2g to 4g of amino acid/kg/day often are necessary, accompanied by sufficient amounts of energy substrates (glucose, lipid emulsion) to satisfy immediate metabolic needs. For paediatric patients, 10% to 20% lipid emulsion infusions can provide up to a maximum of 60% of the patient's daily energy requirements. The other 40% or more should be provided by carbohydrate and amino acids. Both the lipid emulsion dose and these high amino acid doses are upper limits. Levels up to these amounts can be employed; however, lesser amounts are commonly used.

Neonatal and low birth weight patients may exhibit unusual metabolic capacities which should be evaluated regularly during amino acid therapy.

*Note:* It is recommended that all intravenous administration apparatus be replaced at least every 24 hours.

When used in neonates, infants and children, protect from light exposure when admixtures include trace elements and/or vitamins, after admixture through administration. Exposure of Synthamin infusion solutions to ambient light after admixture generates peroxides and other degradation products that can be reduced by protection from light (see section 4.4).

## 4.3 Contraindications

- Hypersensitivity to one or more amino acids or any other active/excipient, or to components of the container
- Patients with renal failure - anuria (for Synthamin with Electrolytes, only)
- Patients with clinically significant elevation of plasma concentrations of sodium, potassium, magnesium and/or phosphorus (for Synthamin with Electrolytes, only)
- Patients with severe liver disease - hepatic coma
- Patients with a congenital abnormality of amino acid metabolism.

## 4.4 Special warnings and precautions for use

1 Do not administer unless solution is clear. This solution should not be administered simultaneously with blood through the same infusion set because of the possibility of pseudoagglutination.

2 Proper administration of Synthamin infusion solutions requires knowledge of fluid and electrolyte balance and nutrition, as well as clinical expertise in recognition and treatment of the complications which may occur. Severe water and electrolyte disorders, severe fluid overload states, and severe metabolic disorders should be corrected before starting the infusion.

Frequent clinical evaluation and laboratory determinations appropriate to the patient's clinical situation and condition are necessary for proper monitoring during administration. Studies should include blood and urine glucose, serum proteins, kidney and liver function tests, water and serum electrolytes, haemogram and carbon dioxide combining power or content, acid/base balance, serum and urine osmolarities, blood cultures and blood ammonia levels.

3 Metabolic complications may occur if the nutrient intake is not adapted to the patient's requirements, or the metabolic capacity of any given dietary component is not accurately assessed. It is essential to provide adequate calories concurrently if parenterally administered amino acids are to be retained by the body and utilised for protein synthesis. Concentrated glucose solutions are an effective source of such calories. Adverse metabolic effects may arise from administration of inadequate or excessive nutrients, or from inappropriate composition of an admixture for a particular patient's needs.

4 With the administration of Synthamin 9 (5.5%) infusion solutions in combination with highly concentrated glucose solutions, hyperglycaemia, glycosuria and hyperosmolar syndrome may result. Blood and urine glucose should be monitored on a routine basis in patients receiving this therapy. In some patients provision of adequate calories in the form of hypertonic glucose may require the administration of exogenous insulin to prevent hyperglycaemia and glycosuria.

5 Sudden cessation in administration of a concentrated glucose solution may result in insulin reaction due to continued endogenous insulin production. Parenteral nutrition mixtures should be withdrawn slowly.

6 Synthamin infusion solutions with electrolytes contain sufficient electrolytes for most parenteral nutrition needs with the possible exception of potassium, where supplementation may be required. Primarily, this is dependent on the amount of carbohydrate administered and metabolised by the patient.

7 Replacement of exceptional electrolyte loss due to nasogastric suction, fistula drainage, or unusual tissue exudation may be necessary. All serum electrolytes should be monitored frequently, especially potassium, phosphate, bicarbonate and chloride.
*Note:* Electrolytes may be added to the Synthamin infusion solutions without electrolytes as dictated by the patient's electrolyte profile.

8 Anaphylactic/anaphylactoid reactions and other hypersensitivity/infusion reactions have been reported with Synthamin infusion solutions administered as a component of parenteral nutrition (see section 4.8). The infusion must be stopped immediately if any signs or symptoms of a reaction develop.

9 Pulmonary vascular precipitates causing pulmonary vascular emboli and pulmonary distress have been reported in patients receiving parenteral nutrition. In some cases, fatal outcomes have occurred. Excessive addition of calcium and phosphate increases the risk of the formation of calcium phosphate precipitates. Precipitates have been reported even in the absence of phosphate salt in the solution. Precipitation distal to the in-line filter and suspected *in vivo* precipitate formation has also been reported.

Pulmonary vascular precipitates have also been reported with Synthamin infusion solutions (see section 4.8). If signs of pulmonary distress occur, the infusion should be stopped and medical evaluation initiated.

In addition to inspection of the solution, the infusion set and catheter should also periodically be checked for precipitates.

10 Infection and sepsis may occur as a result of the use of intravenous catheters to administer parenteral formulations, poor maintenance of catheters or contaminated solutions (see section 4.4/Septic Complications). Immunosuppression and other factors such as hyperglycaemia, malnutrition and/or their underlying disease state may predispose patients to infectious complications. Careful symptomatic and laboratory monitoring for fever/chills, leukocytosis, technical complications with the access device, and hyperglycaemia can help recognise early infections.

11 Refeeding severely undernourished patients may result in the refeeding syndrome that is characterised by the shift of potassium, phosphorus, and magnesium intracellularly as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intakes while avoiding overfeeding can prevent these complications.

12 Patients on parenteral nutrition may experience hepatic complications (including cholestasis, hepatic steatosis, fibrosis and cirrhosis, possibly leading to hepatic failure, as well as cholecystitis and cholelithiasis), and should be monitored accordingly. The aetiology of these disorders is thought to be multifactorial and may differ between patients. Patients developing abnormal laboratory parameters or other signs of hepatobiliary disorders should be assessed by a clinician knowledgeable in liver diseases in order to identify possible causative and contributory factors, and possible therapeutic and prophylactic interventions.

13 Administration of amino acid solutions to a patient with hepatic insufficiency may result in serum amino acid imbalances, hyperammonaemia, stupor and coma. Amino acid solutions should be used with caution in patients with pre-existing liver disease or liver insufficiency. Liver function parameters should be closely monitored in these patients, and they should be monitored for possible symptoms of hyperammonaemia.

Conservative doses of Synthamin infusion solutions should be given to patients with known or suspected hepatic dysfunction. Should symptoms of hyperammonaemia develop, administration should be discontinued and the patient's clinical status re-evaluated.

Commonly reported complications of parenteral nutrition, increased blood ammonia levels, hyperammonaemia and hyperchloraemic metabolic acidosis. Hyperammonaemia appears to be related to a deficiency of the urea cycle amino acids of genetic or product origin. It is essential that blood ammonia be measured frequently in neonates and infants (see section 4.4/Paediatric use).

14 While the potassium, phosphate, metabolisable acetate anion and amino acid profiles in Synthamin Intravenous Infusions with Electrolytes were designed to minimise or prevent occurrences of these imbalances, the physician should be aware that these imbalances may indicate the presence of a congenital disorder of amino acid metabolism and be immediately ready with appropriate counter-measures, if they become necessary.

15 Administration of amino acid solutions, in the presence of impaired renal function presents special dangers associated with retention of added electrolytes. Azotaemia may occur in particular in the presence of renal impairment, and has been reported with parenteral administration of solutions containing amino acids. Use with caution in patients with renal insufficiency. Fluid and electrolyte status should be closely monitored in these patients.

16 Care should be taken to avoid circulatory overload, particularly in patients with cardiac insufficiency, pulmonary oedema, cardiac and/or renal failure. Fluid status should be closely monitored.

17 Hypertonic infusion solutions may cause irritation of the vein when administered into a peripheral vein (see section 4.8). Strongly hypertonic nutrient solutions should be administered through an indwelling intravenous catheter with the tip located in the superior vena cava. Administration of amino acid solutions and other nutrients via central venous catheter may be associated with complications which can be prevented or minimised by careful attention to all aspects of the procedure. This includes attention to solution preparation, administration and patient monitoring. It is essential that a carefully prepared protocol, based on current medical practices be followed, preferably by an experienced team.

18 Light exposure of solutions for intravenous parenteral nutrition, 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 neonates, infants and children, Synthamin infusion solutions should be protected from ambient light after admixture until administration is complete (see section 4.2).

Although a detailed discussion of the complications is beyond the scope of this prescribing information, the following summary lists those based on current literature:

*Technical*
The placement of a central venous catheter should be regarded as a surgical procedure. The physician should be fully acquainted with various techniques of catheter insertion as well as recognition and treatment of complications. For details of techniques and placement sites consult the medical literature. X-ray is the best means of verifying catheter placement. Complications known to occur from the placement of central venous catheters are pneumothorax haemothorax, hydro-thorax artery puncture and transection, injury to the brachial plexus, malposition of the catheter, formation of arteriovenous fistula, phlebitis, thrombosis, cardiac arrhythmia and catheter embolus.

*Septic complications*
The constant risk of sepsis is present during administration of this solution. Since contaminated solutions and infusion catheters are potential sources of infection, it is imperative that the preparation of the solution and the placement and maintenance of catheters be accomplished under controlled aseptic conditions. If fever develops, the solution, its delivery system and the site of the indwelling catheter should be changed.

The occurrence of septic complications can be decreased with heightened emphasis on solution preparation under controlled aseptic conditions such as in the hospital pharmacy under a laminar flow hood. The key factor in their preparation is careful aseptic technique to avoid inadvertent touch contamination during mixing of solutions and addition of other nutrients.

Solutions should be used promptly after mixing. Any storage should be under refrigeration and limited to a brief period of time, preferably less than 24 hours.

*Metabolic*
The following metabolic complications have been reported; metabolic acidosis, hypophosphataemia, alkalosis, hyperglycaemia and glycosuria, osmotic diuresis and dehydration, rebound hypoglycaemia, elevated liver enzymes, hypo and hypervitaminosis, electrolyte imbalances and hyperammonaemia. Frequent clinical evaluation and laboratory determinations are necessary, especially during the first few days of therapy, to prevent or minimise these complications.

*Use in hepatic impairment*
Refer to point 13 above.

*Use in renal impairment*
Refer to point 15 above.

*Use in the elderly*
In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or medicinal therapy.

*Paediatric use*
Hyperammonaemia is of special significance in infants. It is essential that blood ammonia be measured frequently in neonates and infants.

Jaundice in children has been reported in association with administration of some parenteral nutrients containing amino acids. The jaundice appeared to be cholestatic in type; was easily reversed, and there was no evidence of long term toxicity.

No formal studies in children have been performed with Synthamin infusion solutions.

## 4.5 Interaction with other medicines and other forms of interaction

As Synthamin infusion solutions with electrolytes contain potassium, they should be administered with caution in patients treated with agents or products that can cause hyperkalaemia or increase the risk of hyperkalaemia, such as potassium sparing diuretics (amiloride, spironolactone, triamterene), with ACE inhibitors, angiotensin II receptor antagonists, or the immunosuppressants, tacrolimus and cyclosporine.

No formal interaction studies have been performed with Synthamin infusion solutions with/out electrolytes.

## 4.6 Fertility, pregnancy and lactation

*Fertility*

No data are available.

*Use in pregnancy*

Synthamin infusion solutions have not been approved for use in pregnant women. There are no adequate data from the use of Synthamin infusion solutions in pregnant women.

*Use in breast-feeding*

Synthamin infusion solutions have not been approved for use in nursing mothers. There are no adequate data from the use of Synthamin infusion solutions in lactating women.

## 4.7 Effects on ability to drive and use machines

The effects of Synthamin on a person's ability to drive and use machines were not assessed as part of its registration.

## 4.8 Undesirable effects

The following adverse reactions have been reported in the post-marketing experience.

The adverse reactions listed below have been identified from post-marketing reports of Synthamin infusion solutions administered as a component of parenteral nutrition.

IMMUNE SYSTEM DISORDERS: Anaphylactic/anaphylactoid reactions, including skin, gastrointestinal and severe circulatory (shock) and respiratory manifestations as well as other hypersensitivity/ infusion reactions, including pyrexia, chills, hypotension, hypertension, arthralgia, myalgia, urticaria/rash, pruritus, erythema, and headache

VASCULAR DISORDERS: Pulmonary vascular precipitates

The following adverse reactions have been reported with other parenteral amino acid products:

- Azotaemia, hyperammonaemia.

Adverse reactions reported with parenteral nutrition with other similar products to which the amino acid component may play a causal or contributory role include:

- Hepatic failure, hepatic cirrhosis, hepatic fibrosis, cholestasis, hepatic steatosis, blood bilirubin increased, hepatic enzyme increased; cholecystitis, cholelithiasis
- Infusion site thrombophlebitis; venous irritation (infusion site phlebitis, pain, erythema, warmth, swelling, induration).

*Reporting of suspected adverse reactions*
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continuing monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphv.otago.ac.nz/reporting/

### 4.9 Overdose
In the event of inappropriate administration (overdose and/or infusion rate higher than recommended), hypervolaemia, electrolyte disturbances, acidosis and/or azotaemia may occur. In such situations, the infusion must be stopped immediately. If medically appropriate, further intervention may be indicated to prevent clinical complications.

There is no specific antidote for overdose. Emergency procedures should include appropriate corrective measures.

For advice on the management of overdose please contact the National Poisons Centre on phone number: 0800 764 766 [0800 POISON] in New Zealand (or 131126 in Australia).

## 5 PHARMACOLOGICAL PROPERTIES
### 5.1 Pharmacodynamic properties
Synthamin infusion solutions provide a biologically utilisable source material for protein synthesis when administered with adequate calories such as concentrated carbohydrate solutions, vitamins and minerals. This mixture provides (with the exception of essential fatty acids and trace elements) adequate parenteral nutrition.

### 5.2 Pharmacokinetic properties
No data are available.

### 5.3 Preclinical safety data
*Genotoxicity*
No data available.

*Carcinogenicity*
No data available.

## 6 PHARMACEUTICAL PARTICULARS
### 6.1 List of excipients
The excipients are sodium metabisulfite, acetic acid and water for injections.

### 6.2 Incompatibilities
Additives may be incompatible. Do not add other medicinal products or substances without first confirming their compatibility and the stability of the resulting preparation.

Excessive addition of calcium and phosphate increases the risk of the formation of calcium phosphate precipitates (see section 4.4).

### 6.3 Shelf life
24 months from date of manufacture. The expiry date can be found on the packaging.

### 6.4 Special precautions for storage
Store at or below 30°C.

### 6.5 Nature and contents of container

Synthamin infusion solutions with Electrolytes and without Electrolytes are available in 5.5%, 8% and 10% concentrations (see section 2), packed in 500mL bottles.
*Note:* Not all strengths may be marketed.

### 6.6 Special precautions for disposal

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

## 7 MEDICINE SCHEDULE

General Sale Medicine.

## 8 SPONSOR

Synthamin is distributed in New Zealand by:

Baxter Healthcare Ltd
33 Vestey Drive
Mt Wellington
Auckland 1060.

Baxter Healthcare Ltd
PO Box 14 062
Panmure
Auckland 1741

Phone (09) 574 2400.

Synthamin is distributed in Australia by:
Baxter Healthcare Pty Ltd
1 Baxter Drive
Old Toongabbie, NSW 2146.

## 9 DATE OF FIRST APPROVAL

Date of publication in the New Zealand Gazette of consent to distribute the medicine:
18 October 1979.

## 10 DATE OF REVISION OF THE TEXT

30 March 2020.

## SUMMARY TABLE OF CHANGES

| Section changed | Summary of new information |
|---|---|
| 2 | Clarification that Synthamin solutions comprised of essential and non-essential L-amino acids.<br>Removal of 'L-' prefix from amino acids.<br>Excipients referred to section 6.1 |
| 4.2, 4.3, 4.4 | Safety related changes - Information added regarding protect from light exposure |
| 4.7 | Information updated to align with source document |
| 5.3 | Information updated to align with source document |
| 6.3 | Expiry date on packaging added. |
| ALL | Grammar, hyphen usage, Medsafe suggested terminology, capitalization, text relocations |

*Based on Australian PI most recent amendment 26 March 2020; and CCSI425202002Jan.*

*Please refer to the Medsafe website (www.medsafe.govt.nz) for most recent data sheet.*