

SYNTHAMIN INTRAVENOUS INFUSION WITH AND WITHOUT ELECTROLYTES

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about Synthamin Intravenous Infusion, with or without electrolytes (Synthamin). It does not contain all the available information. All medicines have risks and benefits. Your doctor has weighed the risks of you being given Synthamin against the benefits he or she expects it will have for you.

It does not take the place of talking to your doctor, nurse or pharmacist.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet in a safe place.

You may need to read it again.

What Synthamin is used for

Synthamin Infusions are sterile solutions containing different strengths of amino acids, which are building blocks your body uses to make proteins. Some of the strengths of Synthamin also contain electrolytes, which are nutrients your body needs to work properly.

Synthamin is used as a source of nutrition whilst you cannot consume enough food by mouth. It is usually given with other nutrition solutions like mineral and vitamins.

Before you are given Synthamin

Synthamin must not be given to you if you:

- have had an allergic reaction to any of the ingredients of Synthamin - some of the symptoms of an allergic reaction may include skin rash, aches and pains, swelling of the face, lips or tongue which may cause difficulty swallowing or shortness of breath.
- have severe liver disease.
- suffer from severe kidney disease and/or are not producing any urine.
- have too much sodium, potassium, magnesium and/or phosphorus in your blood that is not being correct with medication.
- have an in-born amino acid metabolic disorder.

You should tell your doctor if you:

- suffer from liver disease
- suffer from heart problems
- have a build up of fluid, particularly around the the lungs (pulmonary oedema), ankles (peripheral oedema) or any other condition associated with retaining fluid
- are pregnant or are planning to become pregnant
- are breast-feeding
- are taking any other medicine, including those you can buy without a prescription from your pharmacy, supermarket or health food shop; in particular diuretics, ACE inhibitors or A2RA medicines (commonly used for high blood pressure), or the immunosuppressant medicines tacrolimus or cyclosporin.

How Synthamin is given

How much it is given

Your doctor will decide how much Synthamin you should be given. This will depend on why

you are being given it, and on your condition at the time.

Synthamin will usually be given at the same time as other nutrition solutions such as glucose and fat infusions. These may be mixed together into a single infusion.

How it is given

Synthamin is given as an injection directly into your vein. It is generally given via a large vein. Your doctor or other health professional knows which of your veins to use. Usually you will need to stay in a health institution such as a hospital or nursing home (but in some cases at home) as special equipment is required to deliver the medicine into your circulation. This delivery should be attended by a health professional. A cannula (administration needle) is placed in a vein by your doctor or nurse.

Synthamin is for single use, and for one person only. Any unused portion must be discarded and not used later, either for you or anyone else. Your doctor will decide when to stop giving you this infusion.

Side Effects

As with any medicines, some side effects may occur. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor, nurse or pharmacist if you notice any of the following during or after receiving Synthamin and they worry you.

- administration technique reactions, including fever which may be signs of infection, local pain, irritation, inflammation or reaction (redness, swelling or abnormal clotting) at the site of infusion
- dizziness, weakness, particularly on standing (low blood pressure, or hypotension)

However, if you experience any of the following symptoms, you should tell your doctor or nurse immediately. These may be signs of a very severe or even fatal allergic (hypersensitivity) reaction:

- Swelling of the skin of the face, lips and swelling of the throat
- Difficulty breathing
- Skin rash, or skin redness (erythema) on areas apart from the site of infusion
- Muscle and bone aches and pains
- Fainting

Your health professional will take appropriate action promptly, such as stopping the infusion.

How to store Synthamin

Synthamin will be stored in the pharmacy or on the ward. It is kept in a cool dry place, where the temperature stays below 30°C.

Product Description

What does Synthamin look like?

Synthamin is a clear and virtually colourless solution, contained in a 500mL glass bottle.

Ingredients

There are several strengths of Synthamin Intravenous Solution. Each of these is available with or without added electrolytes (salts).

Inactive Ingredients:

- Sodium Metabisulfite
- Glacial Acetic Acid
- Water for Injections

How to store Synthamin Intravenous Infusion

Synthamin Intravenous Infusion will be stored in the pharmacy or the hospital ward. It is recommended that the product be stored below 30°C.

Where can you get more information?

You can get more information from your doctor or pharmacist.

Name and address of the sponsor

Synthamin Intravenous Infusion is manufactured and supplied in Australia by:

Baxter Healthcare Pty Ltd
1 Baxter Drive
Old Toongabbie NSW
2146

Date of preparation:

April 2014

AUST R Numbers

- **AUST R 19452:** Synthamin 9 Intravenous Infusion
- **AUST R 19451:** Synthamin 9 Intravenous Infusion with Electrolytes
- **AUST R 19448:** Synthamin 13 Intravenous Infusion
- **AUST R 19447:** Synthamin 13 Intravenous Infusion with Electrolytes
- **AUST R 19446:** Synthamin 17 Intravenous Infusion
- **AUST R 19449:** Synthamin 17 Intravenous Infusion with Electrolytes

Active Ingredients:						
	Synthamin 9 Intravenous Infusion	Synthamin 9 Intravenous Infusion With Electrolytes	Synthamin 13 Intravenous Infusion	Synthamin 13 Intravenous Infusion With Electrolytes	Synthamin 17 Intravenous Infusion	Synthamin 17 Intravenous Infusion With Electrolytes
Product Code	AHA6924	AHA6925	AHA6922	AHA6923	AHA6920	AHA6921
Amino Acid Content (%)	5.5	5.5	8.0	8.0	10.0	10.0
Essential Amino Acids (grams per litre)						
L-Leucine	4.02	4.02	5.84	5.84	7.30	7.30
L-Phenylalanine	3.08	3.08	4.48	4.48	5.60	5.60
L-Methionine	2.20	2.20	3.20	3.20	4.00	4.00
L-Lysine (as HCl)	3.19	3.19	4.64	4.64	5.80	5.80
L-Isoleucine	3.30	3.30	4.80	4.80	6.00	6.00
L-Valine	3.19	3.19	4.64	4.64	5.80	5.80
L-Histidine	2.64	2.64	3.84	3.84	4.80	4.80
L-Threonine	2.31	2.31	3.36	3.36	4.20	4.20
L-Tryptophan	0.99	0.99	1.44	1.44	1.80	1.80
Nonessential Amino Acids (grams per litre)						
L-Alanine	11.4	11.4	16.6	16.6	20.70	20.70
L-Glycine	5.66	5.66	8.24	8.24	10.30	10.30
L-Arginine	6.32	6.32	9.20	9.20	11.50	11.50
L-Proline	3.74	3.74	5.44	5.44	6.80	6.80
L-Tyrosine	0.22	0.22	0.32	0.32	0.40	0.40
L-Serine	2.75	2.75	4.00	4.00	5.00	5.00
Electrolytes (grams per litre)						
Sodium Acetate	-	4.31	-	6.80	-	6.80
Dibasic Potassium Phosphate	-	5.22	-	5.22	-	5.22
Sodium Chloride	-	2.24	-	1.17	-	1.17
Magnesium Chloride	-	1.02	-	1.02	-	1.02