Baxter

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

SYNTHAMIN 17, 10% Amino Acid Intravenous Infusion without electrolytes

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet, see section 4.

In this leaflet:

1 What SYNTHAMIN is and what it is used for

2 What you need to know before you are given SYNTHAMIN

3 How SYNTHAMIN is given

4 Possible side effects

5 How SYNTHAMIN is stored

6 Contents of the pack and other information

Throughout this leaflet SYNTHAMIN 17, 10% Amino Acid Intravenous Infusion without electrolytes will be called SYNTHAMIN.

1 What SYNTHAMIN is and what it is used for

SYNTHAMIN is a sterile solution which contains:
- amino acids – these are the building blocks which your body uses to make proteins.

SYNTHAMIN is used to give you food (nutrition) straight into your blood when you cannot take enough food by your mouth.

Your doctor will check your body has all the nutrition that it needs for good health. If necessary, you may also have vitamins (such as folic acid), minerals, fatty acids (the building blocks of fats), electrolytes (salts) and sugar solutions (such as glucose) at the same time as SYNTHAMIN.

2 What you need to know before you are given SYNTHAMIN

SYNTHAMIN must not be given to you if:

- you are allergic (hypersensitive) to any of the ingredients of SYNTHAMIN (listed in section 6) or components of the container
- your body has problems using certain amino acids.

You will not be given SYNTHAMIN if any of the above apply to you.

Warnings and precautions

Talk to your doctor or nurse before SYNTHAMIN is given to you.

SYNTHAMIN will only be used if the solution is clear, free from particles and the container is not damaged.

You will have regular blood and urine tests while being given SYNTHAMIN. This will make sure that you are getting the right amount of solution and if necessary, you will be given other treatments. More checks are made if SYNTHAMIN is being given to a very young child.

If any abnormal signs or symptoms of an allergic reaction develop, such as fever, chills, skin rashes or difficulty in breathing, excessive sweating, nausea, or headache, tell the doctor or the nurse: the infusion will be stopped immediately.

SYNTHAMIN can cause the formation of small particles in your blood. If you start to have difficulty breathing or feel short of breath, tell the doctor or the nurse: the infusion will be stopped immediately, and you may need other treatment.

Certain medications and illnesses can increase the risk of developing infection or sepsis (bacteria in the blood). There is a particular risk of infection or sepsis when a tube (intravenous catheter) is placed in your vein. Your doctor will carefully watch you for any signs of infection. Using aseptic "germ free" techniques when placing and maintaining the catheter and when making the nutritional formula can reduce the risk of infection.

If you are severely malnourished such that you need to receive feeding through a vein, it is recommended that parenteral nutrition is started slowly and carefully.

SYNTHAMIN may cause a stinging pain and redness at the place where it goes into your vein if given into your arm.

Your doctor will monitor your condition at the onset of the infusion, particularly if you currently have liver, kidney, heart, or circulation problems.

Amino acid solutions can increase the level of ammonia or nitrogen-containing compounds in your blood. Your doctor will check your blood tests for this.

Your doctor should also be aware of severe conditions affecting how your body handles fluid, sugars, fats, proteins, or salt (metabolic disorders). These conditions will be corrected before you are given SYNTHAMIN.

When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed. Exposure of SYNTHAMIN to ambient light, especially after admixtures with trace elements and/or vitamins, generates peroxides and other degradation products that can be reduced by protection from light exposure.

Use with other medicines

There are no known problems when SYNTHAMIN is used with other medicines.

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

If you are pregnant, think you might be pregnant or are breast-feeding, tell your doctor. They will decide if you can be given SYNTHAMIN.

3 How SYNTHAMIN is given

Your doctor will decide how much SYNTHAMIN you should be given. It will depend on:

- how much you weigh
- what your body needs
- how much sugar solution (like glucose) you can be given
- why you are being given it.

- **the usual daily dose for children** is 2.2 grams of amino acid (protein) per kilogram
- **the usual daily dose for adults** weighing 70 kilograms is 56 grams of amino acid a day
- these are the recommended amounts to have each day, but you may be given more or less
- SYNTHAMIN is given as an infusion into a large vein in your chest (called the vena cava). The solution is slowly given to you at a rate which will not be more than 70 millilitres per hour.
- You will not be given more than 40 millilitres for every kilogram of your bodyweight in a day.

When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see section 2). You will not be given SYNTHAMIN through the same tubes and equipment used for any blood transfusion.

If you are given too much

Your doctor will give you SYNTHAMIN so it is unlikely that you will be given too much. If you are worried that you have had too much, tell your doctor or nurse.

If the dose given is too high or the infusion too fast, the amino acid content may make your blood too acid, and you may have too much fluid in the circulation.

Giving a volume of SYNTHAMIN that is too large may cause nausea, vomiting, chills, and electrolyte disturbances, in such situations the infusion should be stopped immediately.

In some severe cases, your doctor may have to give you temporary renal dialysis to help your kidneys eliminate the excess product.

To prevent these events occurring, your doctor will regularly monitor your condition and test your blood parameters.

4 Possible side effects

Like all medicines, SYNTHAMIN can cause side effects, although not everybody gets them.
If you notice any changes in the way you feel during or after the treatment, tell your doctor or nurse right away.

The tests your doctor will perform while you are taking the medicine are meant to minimise side effects.

If any abnormal signs or symptoms of an allergic reaction develop, such as abnormally low or high blood pressure, appearance of a blue or purple coloration of the skin, abnormally high heart rate, breathing difficulties, vomiting, nausea, skin rashes, raised body temperature, excessive sweating chills, and shivering, the infusion will be stopped immediately.

Other side effects have been noticed, occurring more or less frequently:

- serious allergic reaction that is rapid in onset and may cause death (anaphylaxis)
- formation of small particles blocking lung blood vessels (pulmonary vascular precipitate).

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

5 How SYNTHAMIN is stored

Keep this medicine out of the sight and reach of children.

SYNTHAMIN should be stored as follows: Do not store above 25ºC and protect it from light.

Do not use SYNTHAMIN after the expiry date which is stated on the label after Exp. The expiry date means the last day of that month.

SYNTHAMIN is for single use only. Partly used bags should not be used again. Any left over solution should be thrown away safely by a healthcare professional. All equipment will be thrown away safely by a healthcare professional after use.

When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see section 2).

6 Contents of the pack and other information

What SYNTHAMIN contains

- The active substances are L-Leucine 0.730% w/v, L-Isoleucine 0.600% w/v, L-Lysine (as hydrochloride salt) 0.580% w/v, L-Valine 0.580% w/v, L-Phenylalanine 0.560% w/v, L-Histidine 0.480% w/v, L-Threonine 0.420% w/v, L-Methionine 0.400% w/v, L-Tryptophan 0.180% w/v, L-Alanine 2.070% w/v, L-Arginine 1.150% w/v, Amino acetic acid (glycine) 1.030% w/v, L-Proline 0.680% w/v, L-Serine 0.500% w/v, L-Tyrosine 0.040% w/v.
- The other ingredient is sterile water (called 'water for injections'). SYNTHAMIN can also sometimes contain a very small amount of glacial acetic acid to adjust the pH of the solution.

What SYNTHAMIN looks like and the contents of the pack

SYNTHAMIN is a solution for infusion (a slow drip injection). It is a clear sterile solution. It is available in sealed plastic bags containing 250 ml, 500 ml, 1,000 ml, 2,000 ml* and 3,000 ml*.

* The 2,000 ml and 3,000 ml bags are bulk bags for a compounding unit to use. They are not meant for use directly in patients.

Marketing Authorisation Holder and Manufacturer

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For information about SYNTHAMIN or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder:
Tel: 01635 206345.

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