

Soluvit®N

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Soluvit N?

Soluvit N contains the active ingredients thiamine nitrate, riboflavine sodium phosphate, nicotinamide, pyridoxine hydrochloride, sodium pantothenate, sodium ascorbate, folic acid, biotin and cyanocobalamin. Soluvit N is a water-soluble vitamins supplement to parenteral nutrition which provides your body with nutrition by the intravenous route. It is usually given together with carbohydrates, amino acids and salts to provide an intravenous diet.

For more information, see Section [1. Why am I using Soluvit N?](#) in the full CMI.

2. What should I know before I use Soluvit N?

Do not use if you have ever had an allergic reaction to any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Soluvit N?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Soluvit N and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Soluvit N?

This medicine is given an infusion into a vein. The dose of Soluvit N which you or your child will require will be determined by your doctor or pharmacist. Your doctor will supervise your or your child's treatment with Soluvit N.

More instructions can be found in Section [4. How do I use Soluvit N?](#) in the full CMI.

5. What should I know while using Soluvit N?

Things you should do	<ul style="list-style-type: none">Remind any health care professional you visit that you are using Soluvit NCall your health care professional straightaway if you have signs and symptoms of allergic reactions. In case of an allergic reaction, the infusion should be stopped immediately, and appropriate measures need to be taken.
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine without consulting your health care professionalDo not take any other medicines without first telling your health care professionalDo not give this medicine to anyone else, even if they have the same condition as you
Driving or using machines	<ul style="list-style-type: none">The effects of this medicine on a person's ability to drive and use machines were not assessed.
Drinking alcohol	<ul style="list-style-type: none">The effects of alcohol with Soluvit N use were not studied.
Looking after your medicine	<ul style="list-style-type: none">This medicine is usually stored in the hospital/clinic, or at the pharmacy, in a cool dry place, protected from light, where the temperature stays below 25°C and children cannot reach it. Each vial is for SINGLE USE in one patient on one occasion only.

For more information, see Section [5. What should I know while using Soluvit N?](#) in the full CMI.

6. Are there any side effects?

Adverse reactions may be expected based on experience with other water-soluble vitamins compounds administered intravenously which include allergic reactions.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Soluvit®N

Active ingredient: *thiamine nitrate, riboflavine sodium phosphate, nicotinamide, pyridoxine hydrochloride, sodium pantothenate, sodium ascorbate, folic acid, biotin and cyanocobalamin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Soluvit N. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Soluvit N.**

Where to find information in this leaflet:

- [1. Why am I using Soluvit N?](#)
- [2. What should I know before I use Soluvit N?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Soluvit N?](#)
- [5. What should I know while using Soluvit N?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Soluvit N?

Soluvit N contains the active ingredients thiamine nitrate, riboflavine sodium phosphate, nicotinamide, pyridoxine hydrochloride, sodium pantothenate, sodium ascorbate, folic acid, biotin and cyanocobalamin.

When the intake of nutrients or food into the mouth or directly into the gut is not possible or not enough to supply the needs, then intravenous nutrients or foods can be given. This is especially important for people under physical stress from illness or recent surgery.

Soluvit N is intended as a supplement in intravenous nutrition to meet the daily requirements of the water-soluble vitamins in adults, adolescents, children and infants. Soluvit N is usually given together with fats, amino acids, glucose and trace elements to provide a complete intravenous diet. Fat-soluble vitamins should also be administered to patients receiving prolonged parenteral nutrition.

2. WHAT SHOULD I KNOW BEFORE I USE SOLUVIT N?

Warnings

Do not use Soluvit N if your or your child:

- are allergic or has known hypersensitivity to to the ingredients of this medicine..

Always check the ingredients to make sure you can use this medicine

Check with your doctor if you or your child:

- have any other medical conditions such as liver or kidney disease
- have severe vitamin deficiency as Soluvit N dose may be insufficient
- have allergies are or your child is allergic to any other medicines or any other substances, such as foods, preservatives or dyes

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Soluvit N can be used by pregnant and breast-feeding women. Check with your doctor if Soluvit N is sufficient to meet the altered requirements in pregnancy and breastfeeding,

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Use in elderly

No data is available for use of Soluvit N in elderly patients. Your doctor will decide what to do.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Soluvit N and affect how it works. These include levodopa and phenytoin.

Other drugs should not be added to Soluvit N dissolved in Intralipid, SMOFlipid or Vitalipid N, due to the possibility of physical incompatibilities.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Soluvit N.

4. How do I use Soluvit N?

How much is given

Your doctor will determine the dose of Soluvit N which you or your child require and will supervise your or your child's treatment with Soluvit N.

How to take Soluvit N

Soluvit N should be dissolved first and then diluted in a bag of amino acids, glucose and/or fats or in clear standard solution. This should be done immediately before the start of the infusion and used within 24 hours. An electronic pump may be used to control the speed of the infusion of drip. The bag containing Soluvit N should be protected from light.

If you forget to use Soluvit N

This rarely happens as Soluvit N is usually administered under the care of a trained health care professional in a hospital or clinic setting.

If you use too much Soluvit N

This rarely happens as Soluvit N is usually administered under the care of a trained professional in a hospital or clinic setting. However, if you think that you have received too much Soluvit N, inform your doctor or nurse immediately.

Your doctor has information on how to recognize and treat an overdose. Ask your doctor if you have any concerns.

If you think that you have used too much Soluvit N, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Soluvit N?

Things you should do

Remind any doctor, dentist, pharmacist or nurse you visit that you are being treated with Soluvit N.

If you are about to have any blood or urine test, tell your health care professional that you are being treated with Soluvit N. It may interfere with the results of some laboratory tests.

Call your doctor straight away if you have signs and symptoms of allergic reactions. In case of an allergic reaction, the infusion should be stopped immediately, and appropriate measures need to be taken.

Looking after your medicine

Soluvit N is usually administered under the care of a trained health care professional in a hospital or clinic setting.

Soluvit N is recommended to be stored below 25°C in a cool dry place, protected from light and away from moisture or heat. Do not freeze.

Do not use after the expiry date which is stated on the carton label and the vial..

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Information below are adverse reactions that may be expected based on other intravenous water-soluble vitamins. Since Soluvit N has to be diluted with other nutrient solutions, these also may cause unwanted effects in some people. If you need to, ask your doctor or nurse if you have any further questions about side effects

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Nausea and vomiting• Shivering• Chills• allergic reactions (skin rash and hives)• breathing difficulties (rapid breathing, shortness of breath)• effects on blood pressure• abdominal pain• tiredness• headaches• dizziness• flushing• slight pressure over the eyes	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• Severe allergic reactions which may include sudden signs of allergy such as rash, itching or hives on the skin or swelling of the face, lips, tongue or other parts of the body	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or nurse if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

This leaflet was prepared in March 2023

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Soluvit N contains

Active ingredient (main ingredient) (quantity in one vial)	thiamine nitrate 3.1 mg, riboflavine sodium phosphate 4.9 mg (corresponding to Vitamin B ₂ 3.6 mg) nicotinamide 40 mg, pyridoxine hydrochloride 4.9 mg (corresponding to Vitamin B ₆ 4.0 mg) sodium pantothenate 16.5 mg (corresponding to pantothenic acid 15 mg) sodium ascorbate 113 mg (corresponding to Vitamin C 100 mg) biotin 60 µg, folic acid 400 µg, cyanocobalamin 5 µg,
Other ingredients (inactive ingredients)	glycine edetate sodium methyl hydroxybenzoate (preservative)
Potential allergens	methyl hydroxybenzoate

Do not take this medicine if you are allergic to any of these ingredients.

Soluvit N does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Soluvit N comes in carton of 10 glass vials. (Aust R 40145)

What Soluvit N looks like

Soluvit N is a yellow lyophilised powder in a glass vial

Who distributes Soluvit N

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