

Solivito® N

Powder for Concentrate for
Solution for Infusion

Read all of this leaflet carefully before you start taking 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4. What is in this leaflet:

1. What Solivito® N is and what it is used for
2. What you need to know before you receive Solivito® N
3. How you are given Solivito® N
4. Possible side effects
5. How to store Solivito® N
6. Contents of the pack and other information

1. What Solivito® N is and what it is used for
Solivito® N provides water-soluble vitamins into your bloodstream when you cannot eat normally. Vitamins are chemicals required in small amounts for the body to work normally.

Solivito® N is usually used as part of a balanced intravenous diet, together with proteins, fat, carbohydrates, other salts and other vitamins.

2. What you need to know before you use Solivito® N

Do not use Solivito® N:

- if you (or your child) are allergic (hypersensitive) to Solivito® N or any of the ingredients of this medicine listed in section 6. If you develop a rash or other allergic reactions (like itching,

swollen lips or face or shortness of breath or bronchospasm), please inform your doctor.

Warnings and Precautions

Your doctor may want to do regular blood tests to check your condition.

This medicine may affect the result of other tests you may have. It is important to tell any doctor doing tests that you are using Solivito® N.

This medicine contains Methyl-parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed), and exceptionally bronchospasm.

Other medicines and Solivito® N

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription.

Inform your doctor if:

- you are taking phenytoin (medicine for epilepsy)
- you are taking any medicine for Parkinson's disease - levodopa
- you are having injections of a drug called hydroxo-cobalamin (used in the treatment of deficiency of vitamin B₁₂ and used in the treatment of some types of eye conditions)

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Solivito® N has no effect on driving or using machines.

3. How you are given Solivito® N

The dissolved and diluted Solivito® N will be given to you by infusion (IV drip).

Your doctor will decide on the correct dose for you to receive.

Other solutions containing carbohydrates, lipids, amino acids, electrolytes and trace elements may be added to this product by the doctor.

Recommended dosage

Adults and children weighing more than 10 kilograms

The usual daily dose for adults and children weighing more than 10 kg is one vial (dissolved to give 10 ml of solution).

Children weighing less than 10 kilograms

For children weighing less than 10 kg, the usual daily dose is one tenth of a vial for each kg of body weight.

If you use more Solivito® N than you should
It is very unlikely that you will receive more infusion than you should as your doctor or nurse will monitor you during the treatment. However if you think that you have received too much Solivito® N, inform your doctor, pharmacist or nurse as soon as possible.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions, including severe allergic (anaphylactic) reactions may occur in patients hypersensitive to any of the ingredients of Solivito® N e.g. folic acid, thiamine or methyl parahydroxybenzoate (frequency not known), see section 6 for the full list.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

UK

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Solivito® N

Keep out of the sight and reach of children
Your doctor and hospital pharmacist are responsible for the correct storage, use and disposal of Solivito® N infusion. Keep the container in the outer carton to protect from light. Do not store above 25°C.

Do not use this medicine after the expiry date shown on the label. The expiry date refers to the last day of that month.

Any solution remaining after treatment should be disposed via approved hospital procedures.

6. Contents of the pack and further information

What Solivito® N contains

Each vial of Solivito® N contains the following active ingredients:

Thiamine Nitrate (B ₁)	3.1 mg
Sodium Riboflavin Phosphate (B ₂)	4.9 mg
Nicotinamide	40 mg
Pyridoxine hydrochloride (B ₆)	4.9 mg
Sodium pantothenate	16.5 mg
Biotin	60 micrograms

Folic acid	0.4 mg
Cyanocobalamin (B ₁₂)	5.0 micrograms
Sodium Ascorbate (Vitamin C)	113 mg

Solivito® N also contains glycine (aminoacetic acid), disodium edetate and methyl parahydroxybenzoate (E218).

What Solivito® N looks like and contents of the pack

Solivito® N is a yellow powder containing water soluble vitamins.

When the powder is dissolved, each vial contains 10 millilitres of solution.

Solivito® N is supplied in cartons containing 10 glass vials with a rubber stopper.

Marketing authorisation holder

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