

Natriumnitriet Hope 30 mg/ml, oplossing voor injectie natriumnitriet

Read all of this leaflet carefully

This leaflet contains information about sodium nitrite, which will have already been given to you by injection into one of your veins.

- Although you will not be taking this medicine yourself, this leaflet contains important information to help you understand how sodium nitrite is used.
- 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.

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1. What sodium nitrite is and what it is used for

Sodium Nitrite 30 mg/mL Solution for Injection is used as an antidote for cyanide poisoning. Cyanide poisoning is a condition that develops when you inhale, touch, or swallow cyanide. Cyanide is a poisonous chemical that prevents your body from absorbing oxygen. The lack of oxygen can damage your organs and be life-threatening.

2. Before you are given sodium nitrite

Your doctor will take special care if you:

- are pregnant or breast-feeding (See Pregnancy and breast-feeding);
- have low blood pressure;
- have a condition called anaemia (This is a reduction in number of red blood cells in the bloodstream. Anaemia can make the skin appear pale and can cause weakness or breathlessness);
- suffer from Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency (This may result in anaemia.);
- have a history of elevated levels of methemoglobin (This is a modified form of hemoglobin that reduces the amount of oxygen in the bloodstream and can cause weakness or breathlessness.);

- have inhaled smoke from a fire;
- have had an allergic reaction to sodium nitrite.

You will be monitored during use with sodium nitrite, and the dose of the medication will be adjusted if necessary.

Using other medicines

The following medicines have side effects that are similar to the side effects that may occur with sodium nitrite.

- Medicines used to treat high blood pressure such as beta blockers, diuretics, and nitrates;
- Medicines that can increase methemoglobin levels such as procaine (used as a local anesthetic) and nitroprusside (used to reduce blood pressure).

It may be necessary for your doctor to adjust the dose of sodium nitrite or one of your other medications.

Do not take sodium nitrite concurrently with hydroxocobalamin.

Pregnancy and breast-feeding

Sodium nitrite should not be used during pregnancy or while breast-feeding. Tell your doctor right away if you are pregnant or breast-feeding.

3. How to sodium nitrite is given

Sodium nitrite will be given by injection into a vein by a doctor or nurse. Your doctor will choose the dose that is right for you.

If signs of cyanide poisoning reappear, your doctor will decide if you should receive more sodium nitrite.

If you have any further questions on the use of sodium nitrite, ask your doctor or nurse.

4. Possible side effects

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

The side effects of sodium nitrite include:

- Heart: reduced blood pressure, rapid heart rate, irregular pulse, transient loss of consciousness, palpitations
- Blood: blood disorder resulting in oxygen deprivation in tissues (methemoglobinemia)
- Head: headache, dizziness, blurred vision, seizures, confusion, coma
- Lungs: difficulty breathing, shortness of breath

- Psychiatric: anxiety
- Stomach and Gut: nausea, vomiting, abdominal pain
- Skin: urticaria (skin rash notable for pale, red, raised, itchy bumps)
- Body as a whole: sweating, light headedness, injection site tingling, fatigue, weakness, generalized numbness and tingling, blue or purple coloured skin

The frequencies at which the above reactions occur are not known yet.

Death was reported after administration of a dose of sodium nitrite that was higher than the recommended therapeutic dose, but less than twice the recommended therapeutic dose.

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 to (to be completed nationally). By reporting side effects you can help provide more information on the safety of this medication.

5. How to store sodium nitrite

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

Do not use this medicine after the expiry date which is stated on the vial label and carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep vial in the outer carton in order to protect from light. For single use only. Use immediately after opening. Discard any unused portions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sodium Nitrite Solution for Injection contains

The active substance is sodium nitrite. Each 10 mL vial contains 300 mg of sodium nitrite (30 mg/mL). The other ingredient is water for injections.

What Sodium Nitrite Solution for Injection looks like and contents of the pack

Sodium Nitrite 30 mg/mL Solution for Injection must be clear and colourless. If particulate matter or discolouration is present, the solution must not be used and should be discarded.

Each carton contains one 10 mL glass vial for single use.

Marketing Authorisation Holder

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In het register ingeschreven onder:

Natriumnitriet Hope 30 mg/ml, oplossing voor injectie RVG 122243

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Natriumnitrit Hope 30 mg/ml Injektionslösung
Belgium	Nitrite de Sodium Hope 30 mg/ml Solution for Injection
France	Nitrite de Sodium Hope 30 mg/ml Solution for Injection
Ireland	Sodium Nitrite Hope Pharmaceuticals 30 mg/ml Solution for Injection
Netherlands	Natriumnitriet Hope 30 mg/ml, oplossing voor injectie
Poland	Sodu azotyn Hope
Spain	Nitrato de Sodio Hope 30 mg/ml Solution for Injection
Sweden	Natriumnitrit Hope 30 mg/ml Solution for Injection
United Kingdom	Sodium Nitrite 30 mg/ml Solution for Injection

Deze bijsluiter is voor het laatst goedgekeurd in juni 2023.