NITHIODOTE Solution for Injection

Active Substances
Sodium Nitrite and Sodium Thiosulfate

Read all of this leaflet carefully

This leaflet contains information about Nithiodote, 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 Nithiodote 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.

In this leaflet

1. What Nithiodote is and what it is used for

Nithiodote is a kit that contains two separate medications: Sodium Nitrite Solution for Injection and Sodium Thiosulfate Solution for Injection.

Nithiodote 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 Nithiodote

Take special care with Nithiodote 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 methaemoglobin (This is a modified form of haemoglobin that reduces the amount of oxygen in the bloodstream and can cause weakness or breathlessness.);
- have inhaled smoke from a fire;
- have had allergic reactions to sulfites.

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

Sodium thiosulfate in Nithiodote contains approximately 3.6 g of sodium per dose and 115 mg of potassium per dose.

Sodium thiosulfate in Nithiodote contains 140 mg of boric acid per dose. If you are pregnant, talk to your doctor before taking this medicine as it contains boron, which may be harmful to your baby.

Using other medicines

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

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

- Medicines used to treat high blood pressure such as beta blockers, diuretics, and nitrates;
- Medicines that can increase methaemoglobin 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.

Nithiodote should not be co-administered with hydroxocobalamin in the same injection line.

Pregnancy and breast-feeding

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

3. How Nithiodote will be given

Nithiodote 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 Nithiodote.

If you have any further questions on the use of Nithiodote, 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:

- Cardiovascular: reduced blood pressure, rapid heart rate, irregular pulse, transient loss of consciousness, palpitations
- Hematological: blood disorder resulting in oxygen deprivation in tissues (methaemoglobinemia)
- Central nervous system: headache, dizziness, blurred vision, seizures, confusion, coma
- Psychiatric: anxiety
- Gastrointestinal: 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 side effects of sodium thiosulfate include:

- Cardiovascular: reduced blood pressure
- Hematological: cuts take longer to stop bleeding than normal
- Central nervous system: headache, disorientation
- Gastrointestinal: nausea, vomiting
- Body as a whole: salty taste in mouth, warm sensation over body

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

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can help make sure that medicines remain as safe as possible by reporting any unwanted side effects directly to www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Nithiodote

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.

Store below 25°C. Store in the outer carton in order to protect from light.

Sodium nitrite and sodium thiosulfate solutions for injection must be clear and colourless. If particulate matter or discolouration is present, the solution must not be used and should be discarded.

For single use only. Sodium nitrite and sodium thiosulfate solutions should be used immediately after opening. Discard any unused portions.

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

6. Contents of the pack and other information

What Nithiodote contains

Each 10 mL vial of Sodium Nitrite Solution for Injection contains 300 mg of the active ingredient sodium nitrite (30 mg/mL).

The other ingredient is water for injections.

Each 50 mL vial of Sodium Thiosulfate Solution for Injection contains 12.5 g of the active ingredient sodium thiosulfate (250 mg/mL). The other ingredients are boric acid, potassium chloride, and water for injections. Sodium hydroxide may also be used to adjust the pH of the solution.

What Nithiodote looks like and contents of the pack

Sodium nitrite and sodium thiosulfate solutions must be clear and colourless. If particulate matter or discolouration is present, the solution must not be used and should be discarded.

Each carton of Nithiodote contains one 10 mL glass vial of Sodium Nitrite Solution for Injection and one 50 mL glass vial of Sodium Thiosulfate Solution for Injection.

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Manufacturer Responsible for Batch Release
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This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland	Nithiodote Solution for Injection
United Kingdom	Nithiodote (Co-Packaged Sodium Nitrite 30mg/ml Solution for Injection and Sodium Thiosulfate 250mg/ml Solution for Injection)

This leaflet was last revised on 28/08/2025.