

Sodium Thiosulfate 250 mg/mL Solution for Injection

sodium thiosulfate

Read all of this leaflet carefully

This leaflet contains information about sodium thiosulfate, 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 Thiosulfate 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 thiosulfate is and what it is used for

Sodium Thiosulfate 250 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 thiosulfate

Your doctor will take special care if you:

- have had an allergic reaction to sulfites.

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

This medicine contains approximately 3.6 g of sodium per vial, equivalent to 180% of the WHO recommended maximum daily intake of 2g sodium for an adult.

This medicine contains 115 mg of potassium per 50ml vial.

This medicine also contains 140 mg of boric acid per 50ml vial. If you are pregnant, talk to your doctor as it contains boron, which may be harmful to your baby.

Using other medicines

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

- Other solutions for injection that contain sodium, such as sodium chloride.

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

Do not take sodium thiosulfate concurrently with hydroxocobalamin.

Pregnancy and breast-feeding

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

3. How sodium thiosulfate is given

Sodium thiosulfate 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 thiosulfate.

If you have any further questions on the use of sodium thiosulfate, 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 thiosulfate include:

- Heart: reduced blood pressure
- Blood: cuts take longer to stop bleeding than normal
- Head: headache, disorientation
- Stomach and Gut: 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medication.

5. How to store sodium thiosulfate

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. 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 dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Sodium Thiosulfate Solution for Injection contains

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

What Sodium Thiosulfate Solution For Injection looks like and contents of the pack

Sodium Thiosulfate 250 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 50 mL single use glass vial.

Marketing Authorisation Holder

Hope Pharmaceuticals, Ltd.

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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	Sodium Thiosulfate Hope Pharmaceuticals 250 mg/ml Solution for Injection
Netherlands	Natriumthiosulfaat Hope 250 mg/ml, Oplossing voor Injectie
Spain	Tiosulfato de Sodio Hope 250 mg/ml Solución Inyectable
Sweden	Natriumtiosulfat Hope 250 mg/ml Injektionsvätska, Lösning
United Kingdom	Sodium Thiosulfate 250 mg/ml Solution for Injection

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