



Package leaflet: Information for the user

Sodium Thiosulfate Seacross 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.

In this leaflet:

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1. What Sodium Thiosulfate Seacross Injection is and what it is used for

The name of your medicine is “Sodium Thiosulfate Seacross 250 mg/mL Solution for Injection” but in the rest of the leaflet it will be called “Sodium Thiosulfate Seacross Injection”. Sodium Thiosulfate Seacross 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 Seacross Injection

Your doctor will take special care if you:

- have had an allergic reaction to sulfites.

You will be monitored during use with Sodium Thiosulfate Seacross Injection, and the dose of the medication will be adjusted if necessary.

This medicine contains approximately 3.6 g of sodium per 50 ml vial, equivalent to 180% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

This medicine contains 115 mg of potassium per 50 ml vial. This medicine also contains 140 mg of boric acid per 50 ml 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 Seacross Injection.

- 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 Seacross Injection or one of your other medications. Do not take sodium thiosulfate concurrently with hydroxocobalamin.

Pregnancy and breast-feeding

Sodium Thiosulfate Seacross Injection 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 Seacross Injection is given

Sodium Thiosulfate Seacross Injection 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 Seacross Injection.

If you have any further questions on the use of Sodium Thiosulfate Seacross Injection, 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 via the Yellow Card Scheme at: 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 Seacross Injection

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.

This medicinal product does not require any special storage conditions.

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 Seacross Injection contains

The active substance is sodium thiosulfate. Each mL solution contains 250 mg of sodium thiosulfate. The other ingredients are boric acid, potassium chloride, sodium hydroxide and water for injections. Sodium hydroxide and boric acid are used to adjust the pH of the solution.

What Sodium Thiosulfate Seacross Injection looks like and contents of the pack

Sodium Thiosulfate Seacross 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.

Sodium Thiosulfate Seacross 250 mg/mL Solution for Injection is supplied in clear glass vials with butyl rubber stoppers and aluminum flip-off seals containing 12.5g (50ml) of sodium thiosulfate. Pack size: 1×50 ml vial.

Marketing Authorisation Holder and Manufacturer

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