SODIUM THIOSULFATE 250 mg/mL Solution for Injection

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:
1. What Sodium Thiosulfate is and what it is used for
2. Before you are given Sodium Thiosulfate
3. How Sodium Thiosulfate will be given
4. Possible side effects
5. How to store Sodium Thiosulfate
6. Further information

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

Take special care with Sodium Thiosulfate if you:
- have had allergic reactions to sulfites.

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

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 Sodium Thiosulfate.

3. How Sodium Thiosulfate will be 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.

- 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.
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 via [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

5. **How to store Sodium Thiosulfate**

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

Do not use Sodium Thiosulfate 250 mg/mL Solution for Injection 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.

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.

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. **Further information**

**What Sodium Thiosulfate contains**

Each 50 mL vial of Sodium Thiosulfate 250 mg/mL 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 Sodium Thiosulfate looks like and contents of the pack**

Each carton of Sodium Thiosulfate 250 mg/mL Solution for Injection contains one 50 mL glass vial.

---

**Marketing Authorisation Holder**
Hope Pharmaceuticals, Ltd.
120 Baker Street
London W1U 6TU
United Kingdom

**Manufacturer**
Cangene bioPharma, Inc.
Baltimore MD 21230
USA

This leaflet was last revised on August 2015.