DBL™ Sodium Thiosulfate Injection

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given DBL Sodium Thiosulfate Injection?

DBL Sodium Thiosulfate Injection contains the active ingredient sodium thiosulfate pentahydrate. It is used for the emergency treatment of cyanide poisoning (often in combination with the medicine sodium nitrite), or to prevent cyanide poisoning when sodium nitroprusside is given.

For more information, see Section 1. Why am I being treated with DBL Sodium Thiosulfate Injection? in the full CMI.

2. What should I know before I am given DBL Sodium Thiosulfate Injection?

Talk to your doctor if you have a sensitivity to sodium thiosulfate or sodium metabisulfite; or any other medical conditions including high blood pressure, liver disease, heart failure, or kidney disease or pre-eclampsia (high blood pressure due to pregnancy).

For more information, see Section <u>2. What should I know before treatment with DBL Sodium Thiosulfate Injection?</u> in the full CMI.

3. What if I am taking other medicines?

Tell your doctor if you are taking any other medicines.

For more information, refer to Section 3. What if I am taking other medicines? in the full CMI.

4. How is DBL Sodium Thiosulfate Injection given?

DBL Sodium Thiosulfate Injection is given as slow injection into a vein.

More instructions can be found in Section 4. How is DBL Sodium Thiosulfate Injection given? in the full CMI.

5. What should I know while I am being given DBL Sodium Thiosulfate Injection?

Things you should do	 Remind any doctor, nurse, pharmacist or dentist you visit that you are being given this medicine. Tell your doctor if you are pregnant or are breastfeeding. Tell your doctor or nurse immediately if you have nausea or vomiting, painful or swollen joints, muscle cramps, blurred vision, hallucinations or abnormal thoughts, or a buzzing/ringing or other persistent noise in the ears.
Driving or using machines	 Be careful driving or using any machines or tools until you know how this medicine affects you. DBL Sodium Thiosulfate Injection may cause blurred vision or low blood pressure, disorientation, hallucinations, strange/disturbing thoughts/behaviour, agitation.
Drinking alcohol	No information available.

For more information, see Section <u>5. What should I know during treatment with DBL Sodium Thiosulfate Injection?</u> in the full CMI.

6. Are there any side effects?

Side effects include: low blood pressure, headache; disorientation; diarrhoea; increased urge to urinate/wee; joint pain or swelling; blurred vision; muscle twitching or cramps; nausea/vomiting; strange or disturbing thoughts/behaviour, agitation, hallucinations (hearing/seeing/feeling things that aren't there), buzzing/hissing/ringing/whistling or other persistent noises in the ears.

Symptoms of an allergic reaction may be serious and they include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, and rash, itching or hives on the skin.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

DBL™ Sodium Thiosulfate

Active ingredient(s): sodium thiosulfate pentahydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Sodium Thiosulfate Injection.

You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about using DBL Sodium Thiosulfate Injection.

Where to find information in this leaflet:

- 1. Why am I being given DBL Sodium Thiosulfate Injection?
- 2. What should I know before I am given DBL Sodium Thiosulfate Injection?
- 3. What if I am taking other medicines?
- 4. How is DBL Sodium Thiosulfate Injection given?
- <u>5.</u> What should I know while I am being given DBL Sodium Thiosulfate Injection?
- 6. Are there any side effects?
- 7. Product details

1. Why am I being given DBL Sodium Thiosulfate Injection?

DBL Sodium Thiosulfate Injection contains the active ingredient sodium thiosulfate pentahydrate.

It belongs to a group of medicines known as antidotes.

DBL Sodium Thiosulfate Injection is used in the emergency treatment of cyanide poisoning, often in combination with the medicine sodium nitrite.

It is also given to prevent cyanide poisoning when sodium nitroprusside is given.

It works by helping the body to convert cyanide into a less dangerous chemical called thiocyanate.

2. What should I know before I am given DBL Sodium Thiosulfate Injection?

Check with your doctor if you:

- have allergies to:
 - o any other medicines
 - o sodium metabisulfite
 - o have had a previous reaction if given sodium thiosulfate
 - o any other substances, such as foods, preservatives or dyes.
- have or have had any other medical conditions, especially the following:
 - o high blood pressure
 - conditions that cause fluid retention, such as liver disease, heart failure, kidney disease or preeclampsia in pregnancy

Pregnancy and breastfeeding

Tell your doctor if you are pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

If you have not told your doctor about any of the above, tell them before you are given this medicine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. <u>Are there any side effects</u>?

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

4. How is DBL Sodium Thiosulfate Injection given?

How much is given

Your doctor will decide what dose you will receive.

How it is given

DBL Sodium Thiosulfate Injection is given as a slow injection into a vein, by a doctor, nurse or trained healthcare professional.

How many injections will you need

Your doctor will decide how long you should continue to be given DBL Sodium Thiosulfate Injection.

If you are given too much DBL Sodium Thiosulfate Injection

As DBL Sodium Thiosulfate Injection is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

Symptoms of overdose may include nausea or vomiting, painful or swollen joints, muscle cramps, blurred vision, hallucinations or abnormal thoughts, or a buzzing/ringing or other persistent noise in the ears.

If you think that you have been given too much DBL Sodium Thiosulfate Injection and/or if you experience severe side effects, you should immediately:

- advise your doctor or nurse
- phone the Poisons Information Centre (by calling 13 11 26), or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include the side effects listed below in Section <u>6. Are there any side effects?</u> but are usually of a more severe nature.

Ask your doctor, nurse or pharmacist if you have any concerns.

5. What should I know while I am being given DBL Sodium Thiosulfate Injection?

Things you should do

Remind any doctor, nurse, pharmacist or dentist you visit that you are being given DBL Sodium Thiosulfate Injection.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given this medicine.

Tell your doctor if you have high blood pressure, or any conditions that cause fluid retention, such as liver disease, heart failure, kidney disease or pre-eclampsia (high blood pressure during pregnancy).

Driving or using machines

Be careful driving or using any machines or tools until you know how DBL Sodium Thiosulfate Injection affects you.

Sodium thiosulfate may cause blurred vision, low blood pressure (which can result in dizziness, light-headedness, unsteadiness, fainting, confusion or tiredness) or disorientation or hallucinations.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

No information available.

Looking after your medicine

DBL Sodium Thiosulfate Injection will be stored in the pharmacy or on the ward.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effect	What to do
 low blood pressure dizziness or light headedness headache disorientation diarrhoea increased urge to urinate/wee 	Tell your doctor or nurse if you notice any of the following during treatment

Side effect	What to do
 joint pain or swelling blurred vision muscle twitching or cramps nausea and vomiting strange or disturbing thoughts or behaviour, including feeling agitated or having hallucinations (seeing, feeling or hearing things that are not there) buzzing, hissing, whistling, ringing or other persistent noises in the ears Symptoms of an allergic reaction may include: 	Tell your doctor or nurse immediately if you notice any of the following These may be more serious side effects. You may need urgent medical attention. Serious side effects are rare.
 shortness of breath wheezing or difficulty breathing swelling of the face, lips, tongue or other parts of the body rash, itching or hives in the skin. 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/safety/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop treatment with any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What DBL Sodium Thiosulfate Injection contains

Active ingredient (main ingredient)	Sodium thiosulfate pentahydrate
Other ingredients (inactive	Dibasic sodium phosphate dodecahydrate
ingredients)	Sodium metabisulfite
	Hydrochloric acid
	Sodium chloride
	Water for Injections

DBL Sodium Thiosulfate Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What DBL Sodium Thiosulfate Injection looks like

DBL Sodium Thiosulfate Injection is a clear, colourless solution.

DBL Sodium Thiosulfate Injection is available as follows:

• 2.5 g/10 mL vials (1 per pack) (AUST R 133490)

Who distributes DBL Sodium Thiosulfate Injection

Pfizer Australia Pty Ltd Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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