Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL $^{\rm TM}$ Sodium Nitrite Injection.

It does not contain all the available information. It does not take the place of talking to your doctor and pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given DBLTM Sodium Nitrite Injection against the benefits this medicine is expected to have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist. Keep this leaflet in a safe place.

You may need to read it again.

What DBL™ Sodium Nitrite Injection is used for

DBL™ Sodium Nitrite Injection is used in the emergency treatment of cyanide poisoning.

DBL™ Sodium Nitrite Injection works by helping to prevent cyanide from binding to important enzymes in the cells of your body.

Your doctor may have prescribed DBLTM Sodium Nitrite Injection for another reason. Ask your doctor if you have any questions about why DBLTM Sodium Nitrite Injection has been prescribed for you.

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

Before you are given DBL™ Sodium Nitrite Injection

When you must not be given it

 $DBL^{\scriptscriptstyle TM}$ Sodium Nitrite Injection should not be given to you if:

- you are suffering from smoke inhalation and combined carbon monoxide and cyanide poisoning
- you have an allergy to sodium nitrite or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to sodium nitrite may include skin rash, itching, difficulty breathing and swelling, especially of the face and throat.

- the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed.
 If you are given this medicine after the
 expiry date has passed, it may not work as
 well.

Before you are given it

Your doctor should know about all the following before you are given $DBL^{\rm TM}$ Sodium Nitrite Injection:

- if you have or have ever had any other health problems/medical conditions, including:
- a condition called methaemoglobinaemia, which is a condition of the blood,
- hypotension or low blood pressure,
- a deficiency of glucose-6-phospate dehydrogenase.
- 2. if you are pregnant or intend to become pregnant

Your doctor will discuss the risks and benefits of using Sodium Nitrite Injection during pregnancy.

3. if you are breast-feeding or plan to breast-feed

Your doctor will discuss the risks and benefits of using Sodium Nitrite Injection when breast-feeding.

If you have not told your doctor about any of the above, tell them before you are given DBL^{TM} Sodium Nitrite Injection.

How DBL™ Sodium Nitrite Injection is given

DBLTM Sodium Nitrite Injection is given as an injection into a vein.

$DBL^{\rm TM}$ Sodium Nitrite Injection should only be given by a doctor or nurse or other trained person.

In emergency situations it may be necessary for the injection to be given by a health professional other than a doctor or nurse (such as an ambulance officer).

Your doctor will decide what dose of DBLTM Sodium Nitrite Injection you will require and how long you will receive it. This depends on your medical condition and other factors, such as your weight.

If you take too much (overdose)

As DBLTM Sodium Nitrite for Injection is given to you under the supervision of a health care professional, it is very unlikely that you will receive too much. However, if you experience any severe side effects after being given DBLTM Sodium Nitrite for Injection, tell your doctor immediately or go to Accident and Emergency at the nearest hospital.

You may need urgent medical attention

In case of overdose, immediately contact the Poisons Information Centre for advice (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand).

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given DBL^{TM} Sodium Nitrite Injection.

DBLTM Sodium Nitrite Injection may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

While being given it

Tell your doctor immediately if you notice any of the following:

- nausea, vomiting or abdominal pain
- headache or dizziness
- · fast heart beat
- · fast or distressed breathing
- blue finger nails or lips

Some people may get other side effects while being given DBLTM Sodium Nitrite Injection.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After being given DBL™ Sodium Nitrite Injection

Storage

DBL $^{\text{TM}}$ Sodium Nitrite Injection will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place where the temperature stays below 25°C, and it is protected from light.

After use, any unused portion of the ampoule should be discarded

Product description

What it looks like

DBLTM Sodium Nitrite Injection is a clear, colourless solution.

Ingredients

DBLTM Sodium Nitrite Injection contains 300mg sodium nitrite as the active ingredient.

It also contains:

· water for injection.

 $DBL^{\rm TM}$ Sodium Nitrite Injection does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Sponsor

DBLTM Sodium Nitrite Injection is supplied by:

Australian Sponsor:

Hospira Australia Pty Ltd ABN 58 097 064 330 Level 3 500 Collins Street Melbourne VIC 3000 Australia

New Zealand Sponsor:

Hospira NZ Limited 23 Haining Street Te Aro Wellington New Zealand

DBLTM Sodium Nitrite Injection is available in the following strength:

 300 mg/10 mL, x5 ampoules. AUST R 16290

This leaflet was prepared in September 1998 and reviewed in November 2011.