

DBL™ Glyceryl Trinitrate Concentrate 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 treated with DBL Glyceryl Trinitrate Concentrate Injection?

DBL Glyceryl Trinitrate Concentrate Injection contains the active ingredient glyceryl trinitrate. DBL Glyceryl Trinitrate Concentrate Injection is used to relax the muscles surrounding blood vessels (arteries and veins) and so helps more blood and oxygen reach the heart. It is also used to control or lower the blood pressure during some surgical procedures.

For more information, see Section [1. Why am I being treated with DBL Glyceryl Trinitrate Concentrate Injection?](#) in the full CMI.

2. What should I know before treatment with DBL Glyceryl Trinitrate Concentrate Injection?

Do not start treatment if you have ever had an allergic reaction to glyceryl trinitrate, any medicine or food containing nitrates, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before treatment with DBL Glyceryl Trinitrate Concentrate Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Glyceryl Trinitrate Concentrate Injection and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is DBL Glyceryl Trinitrate Concentrate Injection given?

Your doctor will decide how much DBL Glyceryl Trinitrate Concentrate Injection you will receive. This depends on your condition and other factors, such as your age and weight.

More instructions can be found in Section [4. How is DBL Glyceryl Trinitrate Concentrate Injection given?](#) in the full CMI.

5. What should I know during treatment with DBL Glyceryl Trinitrate Concentrate Injection?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, nurse, dentist or pharmacist who is treating you that you are being treated with DBL Glyceryl Trinitrate Concentrate Injection.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how DBL Glyceryl Trinitrate Concentrate Injection affects you.

	<ul style="list-style-type: none"> • This medicine may cause dizziness, light-headedness, fainting and headache in some people. If this occurs do not drive or do anything else that could be dangerous.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol. • If you drink alcohol, dizziness or light-headedness may be worse.

For more information, see Section [5. What should I know during treatment with DBL Glyceryl Trinitrate Concentrate Injection?](#) in the full CMI.

6. Are there any side effects?

Common side effects include headache and dizziness. Less common side effects include: rapid or irregular heart beat, bleeding easily, swelling, nausea, vomiting or abdominal pain, pins and needles, tiredness, sleepiness, state of confusion, seizure, muscle twitching or restlessness, muscle weakness, shoulder, neck and upper body pain, abdominal tenderness of the right upper quadrant, dry mouth, frequent urination, shortness of breath, vision problems.

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™ Glyceryl Trinitrate Concentrate Injection

Active ingredient(s): glyceryl trinitrate (GLIS-er-ile tri-NITE-rate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Glyceryl Trinitrate Concentrate Injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being treated with DBL Glyceryl Trinitrate Concentrate Injection.**

Where to find information in this leaflet:

- [1. Why am I being treated with DBL Glyceryl Trinitrate Concentrate Injection?](#)
- [2. What should I know before treatment with DBL Glyceryl Trinitrate Concentrate Injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is DBL Glyceryl Trinitrate Concentrate Injection given?](#)
- [5. What should I know during treatment with DBL Glyceryl Trinitrate Concentrate Injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being treated with DBL Glyceryl Trinitrate Concentrate Injection?

DBL Glyceryl Trinitrate Concentrate Injection contains the active ingredient glyceryl trinitrate. Glyceryl trinitrate belongs to a group of medicines called nitrates or vasodilators.

DBL Glyceryl Trinitrate Concentrate Injection is used to relax the muscles surrounding blood vessels (arteries and veins) and so helps more blood and oxygen reach the heart.

It is also used to control or lower the blood pressure during some surgical procedures.

Your doctor may have prescribed glyceryl trinitrate for another reason. Ask your doctor if you have any questions about why glyceryl trinitrate has been prescribed for you.

Glyceryl trinitrate is not addictive.

2. What should I know before treatment with DBL Glyceryl Trinitrate Concentrate Injection?

Warnings

You must not be given DBL Glyceryl Trinitrate Concentrate Injection if:

- you are allergic to:
 - glyceryl trinitrate, or any of the ingredients listed at the end of this leaflet.
 - any medicine or food containing nitrates

Symptoms of an allergic reaction to glyceryl trinitrate may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Always check the ingredients to make sure you can use this medicine.

- you have any of the following conditions:
 - low blood pressure
 - increased pressure in the head (such as a recent head injury or stroke)
 - disease of the heart muscle or swelling around the heart
 - reduced red blood cells and iron stores (anaemia) or a lack of oxygen in the blood
 - an abnormality of haemoglobin, part of your red blood cells, responsible for carrying oxygen.
- you are taking the following medicines:
 - phosphodiesterase inhibitors, such as sildenafil, vardenafil or tadalafil used to treat impotence in men and/or for treating high blood pressure in the lungs in men and women.
 - riociguat used to treat high blood pressure in your lungs.

If you use these medicines together with DBL Glyceryl Trinitrate Concentrate Injection, your blood pressure may fall to a dangerously low level.

If you are not sure whether you should be given DBL Glyceryl Trinitrate Concentrate Injection, talk to your doctor or pharmacist.

Check with your doctor if you:

- have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.

- have or have had any other medical conditions especially the following:
 - liver disease
 - kidney disease
 - a recent heart attack or any heart condition for which you already use a nitrate vasodilator drug such as patches or sprays containing a nitrate
 - heart disease caused by poor blood flow in the arteries of the heart
 - any other heart condition
 - any lung condition
 - closed angle glaucoma
- take any medicines for any other condition

If you have not told your doctor or pharmacist about any of the above, tell them before you are given DBL Glyceryl Trinitrate Concentrate Injection.

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Glyceryl trinitrate is not recommended for use during pregnancy. If there is a need to consider glyceryl trinitrate during your pregnancy, your doctor or pharmacist will discuss with you the benefits and risks of using it.

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

Glyceryl trinitrate is not recommended while you are breastfeeding. It is not known if glyceryl trinitrate is excreted into breast-milk.

Use in Children

Glyceryl trinitrate is not recommended for use in children, as there is not enough information on its effects in children.

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.

Some medicines and DBL Glyceryl Trinitrate Concentrate Injection may interfere with each other and affect how they work. These include:

- aspirin and other non-steroidal anti-inflammatory medicines
- morphine, a medicine used for pain
- some medicines for depression such as tricyclic antidepressants
- some medicines that block nerve conduction to muscles such as anticholinergics
- heparin, a medicine used to prevent blood clots

- some medicines used to treat high blood pressure or heart problems
- ergotamine, methysergide and dihydroergotamine; medicines used to prevent or treat migraine headaches
- tranquillisers, medicines used to treat some mental illnesses
- some medicines for impotence such as sildenafil
- riociguat used to treat high blood pressure in your lungs.

These medicines may be affected by glyceryl trinitrate or may affect how well it works. You may need different amounts of your medicines, or you may need to take or use different medicines. Your doctor or pharmacist will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Glyceryl Trinitrate Concentrate Injection.

4. How is DBL Glyceryl Trinitrate Concentrate Injection given?

How much is given

Due to variations in the response of individual patients to the drug, the dose of glyceryl trinitrate varies. Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your age or weight.

How it is given

DBL Glyceryl Trinitrate Concentrate Injection must be diluted and given as a slow infusion or 'drip' injection into your veins (intravenously). It should not be mixed with other drugs.

If you are given too much DBL Glyceryl Trinitrate Concentrate Injection

As DBL Glyceryl Trinitrate Concentrate Injection is given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience severe side effects tell your doctor immediately.

Symptoms of a glyceryl trinitrate overdose include the side effects listed below in Section 6. Are there any side effects? but are usually of a more severe nature.

Ask your doctor or pharmacist if you have any concerns.

If you think that you have been given too much DBL Glyceryl Trinitrate Concentrate Injection, you may need urgent medical attention.

You should immediately:

- contact your doctor, or
- 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.

5. What should I know during treatment with DBL Glyceryl Trinitrate Concentrate Injection?

Things you should do

Remind any doctor, nurse, dentist or pharmacist who is treating you that you are being treated with DBL Glyceryl Trinitrate Concentrate Injection.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL Glyceryl Trinitrate Concentrate Injection affects you.

DBL Glyceryl Trinitrate Concentrate Injection may cause dizziness, light-headedness, fainting and headache in some people.

Make sure you know how glyceryl trinitrate affects you before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol, dizziness or light-headedness may be worse.

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.

Common side effects

Common side effects	What to do
General <ul style="list-style-type: none">• headache• dizziness	Speak to your doctor if you have any of these common side effects and they worry you. Mostly these are short-lived.

Less common side effects

Less common side effects	What to do
<p data-bbox="204 488 746 533">Heart and blood related</p> <ul data-bbox="204 568 772 810" style="list-style-type: none"><li data-bbox="204 568 772 676">● rapid or slow or irregular heart beat<li data-bbox="204 698 571 743">● bleeding easily<li data-bbox="204 766 421 810">● swelling <p data-bbox="204 837 580 882">Stomach related</p> <ul data-bbox="204 918 676 1025" style="list-style-type: none"><li data-bbox="204 918 676 1025">● nausea, vomiting or abdominal pain <p data-bbox="204 1052 746 1097">Nervous system related</p> <ul data-bbox="204 1133 667 1438" style="list-style-type: none"><li data-bbox="204 1133 612 1178">● pins and needles<li data-bbox="204 1200 443 1245">● tiredness<li data-bbox="204 1267 667 1375">● sleepiness, state of confusion<li data-bbox="204 1397 405 1442">● seizure <p data-bbox="204 1464 539 1509">Muscle related</p> <ul data-bbox="204 1545 660 1720" style="list-style-type: none"><li data-bbox="204 1545 660 1653">● muscle twitching or restlessness<li data-bbox="204 1675 628 1720">● muscle weakness <p data-bbox="204 1747 686 1854">Pain or discomfort in your body</p> <ul data-bbox="204 1890 660 1998" style="list-style-type: none"><li data-bbox="204 1890 660 1998">● shoulder, neck and upper body pain	<p data-bbox="817 488 1378 649">Call your doctor straight away if you notice any of these side effects.</p>

Less common side effects	What to do
<ul style="list-style-type: none"> ● abdominal tenderness of the right upper quadrant <p>Mouth related</p> <ul style="list-style-type: none"> ● dry mouth <p>Urinary related</p> <ul style="list-style-type: none"> ● frequent urination <p>Respiratory related</p> <ul style="list-style-type: none"> ● shortness of breath <p>Eye related</p> <ul style="list-style-type: none"> ● vision problems 	

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/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 Glyceryl Trinitrate Concentrate Injection contains

Active ingredient (main ingredient)	glyceryltrinitrate
Other ingredients (inactive ingredients)	ethanol absolute propylene glycol water for injections

DBL Glyceryl Trinitrate Concentrate Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Do not use this medicine if you are allergic to any of these ingredients.

What DBL Glyceryl Trinitrate Concentrate Injection looks like

DBL Glyceryl Trinitrate Concentrate Injection is a clear, practically colourless solution (Aust R 16341).

DBL Glyceryl Trinitrate Concentrate Injection is available in the following strength and pack:

- 50mg in 10mL, 5 x 10mL ampoules

How is DBL Glyceryl Trinitrate Concentrate Injection stored

DBL Glyceryl Trinitrate Concentrate Injection will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Who distributes DBL Glyceryl Trinitrate Concentrate Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedinfo.com.au

This leaflet was prepared in June 2022.

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