

DBL™ Promethazine Hydrochloride Injection BP

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 Promethazine Hydrochloride Injection BP?

DBL Promethazine Hydrochloride Injection BP contains the active ingredient promethazine hydrochloride. DBL Promethazine Hydrochloride Injection BP is used to treat allergic reactions, to relieve nausea, vomiting and dizziness and/or as a sedative.

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

2. What should I know before treatment with DBL Promethazine Hydrochloride Injection BP?

Do not use if you have ever had an allergic reaction to promethazine hydrochloride, phenothiazine-derivative medicines 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 Promethazine Hydrochloride Injection BP?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Promethazine Hydrochloride Injection BP 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 Promethazine Hydrochloride Injection BP given?

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight. It must only be given by a doctor or nurse.

More instructions can be found in Section [4. How is DBL Promethazine Hydrochloride Injection BP given?](#) in the full CMI.

5. What should I know during treatment with DBL Promethazine Hydrochloride Injection BP?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, nurse, pharmacist or dentist who treat you that you are being given this medicine. Remind them before starting a new medicine, before surgery and blood tests.• Use a sunscreen on exposed skin or remain covered if you go outdoors after being given this medicine. DBL Promethazine Hydrochloride Injection BP may cause you to sunburn more easily.
Things to be careful of	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how DBL Promethazine

	<p>Hydrochloride Injection BP affects you.</p> <ul style="list-style-type: none"> • Children should be careful when riding bicycles or climbing trees.
Drinking alcohol	<ul style="list-style-type: none"> • Be careful when drinking alcohol while being given this medicine. • If you drink alcohol, dizziness or drowsiness may be worse.

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

6. Are there any side effects?

Side effects include: dry mouth, nose or throat, injection site reaction, nausea and vomiting, constipation or diarrhoea, loss of appetite, unusual tiredness or weakness, clumsiness or unsteadiness, feeling faint, difficulty in sleeping, increased sensitivity of the skin to the sun, and skin itch.

Serious side effects include: sore throat and fever, blurred vision, difficult or painful urination, fast or slow heartbeat, severe drowsiness, confusion, tremors or convulsions, muscle spasms in the neck and back, jerky movements of the head and face, shuffling walk, trembling and shaking of hands, ringing or buzzing in ears, unusual excitement, nervousness, restlessness or

irritability, hallucinations, aggression, trouble breathing, flushing or redness of face, allergic reaction symptoms, severe pain in the stomach with bloating, gut cramps and vomiting, unusual bleeding or bruising, and yellowing of the skin or eyes.

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™ Promethazine Hydrochloride Injection BP

Active ingredient(s): *Promethazine hydrochloride*
(Proe-METH-a-zeen)

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Promethazine Hydrochloride Injection BP. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DBL Promethazine Hydrochloride Injection BP.**

Where to find information in this leaflet:

1. Why am I being treated with DBL Promethazine Hydrochloride Injection BP?
2. What should I know before treatment with DBL Promethazine Hydrochloride Injection BP?
3. What if I am taking other medicines?
4. How is DBL Promethazine Hydrochloride Injection BP given?
5. What should I know during treatment with DBL Promethazine Hydrochloride Injection BP?
6. Are there any side effects?
7. Product details

1. Why am I being treated with DBL Promethazine Hydrochloride Injection BP?

DBL Promethazine Hydrochloride Injection BP contains the active ingredient promethazine hydrochloride. DBL Promethazine Hydrochloride Injection BP belongs to a group of antihistamines called phenothiazines (fen-oh-THY-ah-zines). It works by preventing the effects of histamine in the body.

DBL Promethazine Hydrochloride Injection BP is used to treat:

- allergic reactions,
- to relieve nausea, vomiting and dizziness
- as a sedative (to help people go to sleep and control their anxiety) before and after surgery, and during labour.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

2. What should I know before treatment with DBL Promethazine Hydrochloride Injection BP?

Warnings

You must not be given DBL Promethazine Hydrochloride Injection BP if:

1. you are allergic to:
 - any medicine containing promethazine hydrochloride
 - any other phenothiazine-derivative medicines or
 - any of the ingredients listed at the end of this leaflet, such as sulfites.

Some of the symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips or 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.

2. the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged return it to your pharmacist for disposal.

If you are not sure whether you should be given this medicine, talk to your doctor.

Check with your doctor if you:

- have any allergies to any other medicines, foods, preservatives or dyes.
- have or have had any other medical conditions, especially the following:
 - asthma or breathing difficulties
 - bone-marrow depression
 - enlarged prostate
 - epilepsy
 - heart or blood pressure disease
 - irregular heart beat
 - glaucoma, an eye condition
 - liver problems
 - ulcer of the stomach or duodenum
 - kidney or bladder problems
- take any medicines for any other condition, including sedatives

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

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.

DBL Promethazine Hydrochloride Injection BP is not recommended for use during later stages of pregnancy. If there is a need to consider promethazine during pregnancy, your doctor will discuss with you the benefits and risks of being given it.

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

Promethazine passes into breast milk and there is a possibility that your baby may be affected.

Your doctor or pharmacist will discuss the possible risks and benefits of being given promethazine while you are breastfeeding.

Use in Children

This medicine must not be given to children under the age of 2 years.

Safety and effectiveness in children under the age of 2 years have not been established.

In general, children are more sensitive to the effects of antihistamines, and DBL Promethazine Hydrochloride Injection BP should be administered with caution.

Serious side effects, such as convulsions, are more likely to occur in younger patients and would be of greater risk to infants than to older children or adults. Also, nightmares or hallucinations, unusual or excessive hyperactivity or excitement, nervousness, aggression, restlessness, or irritability may be more likely to occur in children.

The use of this medicine is not recommended in children who have a history of difficulty in breathing while sleeping or a family history of sudden infant death syndrome (SIDS), or in children under 2 years of age.

Children or adolescents who show signs of Reye's syndrome should not be given this medicine.

Uncontrolled movements that may occur with promethazine may be mistakenly confused with symptoms of Reye's syndrome.

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 may interfere with DBL Promethazine Hydrochloride Injection BP and affect how it works.

These include:

- anticholinergic medicines, including medicines for stomach spasm
- anticonvulsants or medicines for epilepsy/fits/seizures
- beta blockers such as propranolol, medicines used to lower blood pressure
- bromocriptine, a medicine used to treat Parkinson's disease, acromegaly or to prevent lactation
- medicines that cause drowsiness or sleepiness such as sedatives, tranquillisers, barbiturates,

antihistamines, opioid analgesics (medicine to treat pain), general anaesthetics and alcohol

- levodopa (medicine for Parkinson's disease)
- metrizamide, a contrast agent, injected into the spinal cord before an x-ray
- medicines used to treat depression, especially monoamine oxidase (MAO) inhibitors and tricyclic antidepressants
- phenothiazine-derivative medicines e.g. chlorpromazine (medicine for thought disorder)
- quinidine, a medicine for rapid or irregular heartbeat
- medicines to treat cold and flu
- appetite suppressants

These medicines may be affected by promethazine or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while being treated with this medicine.

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 Promethazine Hydrochloride Injection BP.

4. How is DBL Promethazine Hydrochloride Injection BP given?

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight.

How it is given

DBL Promethazine Hydrochloride Injection BP is given as:

- a deep injection into a large muscle or
- as a slow injection into a vein.

It must only be given by a doctor or nurse.

If you receive too much DBL Promethazine Hydrochloride Injection BP

As DBL Promethazine Hydrochloride Injection BP is given to you under the supervision of your doctor, it is unlikely that you will receive an overdose.

If you experience severe side effects or you think that you have been given too much DBL Promethazine Hydrochloride Injection BP, 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.

Symptoms of an overdose may include the side effects listed under 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.

5. What should I know during treatment with DBL Promethazine Hydrochloride Injection BP?

Things you should do

- **Remind any doctor, nurse, pharmacist or dentist who treat you that you are being given DBL Promethazine Hydrochloride Injection BP.**

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are being given DBL Promethazine Hydrochloride Injection BP.

- **If you are going to have surgery, tell the surgeon or anaesthetist that you are being given this medicine.**

It may affect other medicines used during surgery.

- **If you are about to have any blood tests, tell your doctor that you are being given this medicine.**

It may interfere with the results of some tests including pregnancy, glucose and skin allergen tests.

- **Use a sunscreen on exposed skin or remain covered if you go outdoors after being given DBL Promethazine Hydrochloride Injection BP.**

This medicine may cause you to sunburn more easily.

Things to be careful of

Be careful before you drive or use any machines or tools until you know how DBL Promethazine Hydrochloride Injection BP affects you.

DBL Promethazine Hydrochloride Injection BP may cause drowsiness, dizziness or sleepiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Children should be careful when riding bicycles or climbing trees.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while being given this medicine.

If you drink alcohol, dizziness or drowsiness 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.

If you are over 65 years of age you may have an increased chance of getting side effects.

Side effects

Side effects	What to do
General <ul style="list-style-type: none">• dry mouth, nose or throat• injection site reaction Stomach related issues <ul style="list-style-type: none">• nausea and vomiting• constipation or diarrhoea• loss of appetite Central Nervous System <ul style="list-style-type: none">• unusual tiredness or weakness	Speak to your doctor, nurse or pharmacist if you have any of these side effects and they worry you.

Side effects	What to do
<ul style="list-style-type: none"> • clumsiness or unsteadiness • feeling faint • difficulty in sleeping • aggression • unusual or excessive hyperactivity <p>Skin related issues</p> <ul style="list-style-type: none"> • increased sensitivity of the skin to the sun • skin itch 	

Serious side effects

Serious side effects	What to do
<p>General</p> <ul style="list-style-type: none"> • sore throat and fever <p>Eye issues</p> <ul style="list-style-type: none"> • blurred vision <p>Urinary related issues</p> <ul style="list-style-type: none"> • difficult or painful urination <p>Heart related issues</p> <ul style="list-style-type: none"> • fast or slow heartbeat <p>Central nervous system</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these side effects.</p> <p>These may be serious side effects. You may need urgent medical attention.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● severe drowsiness ● confusion ● tremors or convulsions ● muscle spasms in the neck and back ● jerky movements of the head and face ● shuffling walk ● trembling and shaking of hands ● ringing or buzzing in ears <p>Changes in behaviour, thinking or mood</p> <ul style="list-style-type: none"> ● unusual excitement, nervousness, restlessness or irritability ● hallucinations <p>Respiratory issues</p> <ul style="list-style-type: none"> ● trouble breathing <p>Skin issues</p> <ul style="list-style-type: none"> ● flushing or redness of face <p>Allergic reaction symptoms</p>	

Serious side effects	What to do
<ul style="list-style-type: none"> • shortness of breath, wheezing or difficulty breathing • swelling of the face, lips or tongue or other parts of the body • rash, itching or hives on the skin. <p>Stomach related issues</p> <ul style="list-style-type: none"> • severe pain in the stomach with bloating, gut cramps and vomiting <p>Blood related issues</p> <ul style="list-style-type: none"> • unusual bleeding or bruising <p>Liver related issues</p> <ul style="list-style-type: none"> • yellowing of the skin or eyes (jaundice) 	

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. Some side effects may only be found when your doctor does tests from time to time to check your progress.

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 Promethazine Hydrochloride Injection BP contains

Active ingredient (main ingredient)	promethazine hydrochloride
Other ingredients (inactive ingredients)	disodium edetate glacial acetic acid sodium acetate sodium metabisulfite water for injections

DBL Promethazine Hydrochloride Injection BP contains 50 mg/ 2 mL of promethazine hydrochloride.

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

This medicine does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

What DBL Promethazine Hydrochloride Injection BP looks like

DBL™ Promethazine Hydrochloride Injection BP is a clear, colourless solution. (Aust R 16255).

How DBL Promethazine Hydrochloride Injection BP is stored

DBL Promethazine Hydrochloride Injection BP 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 Promethazine Hydrochloride Injection BP

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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