

DBL™ Promethazine Hydrochloride Injection BP

Promethazine hydrochloride (*Proe-METH-a-zeen*)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Promethazine Hydrochloride Injection BP (Promethazine). 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 DBL™ Promethazine Hydrochloride Injection BP against the benefits they expect it will 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™ Promethazine Hydrochloride Injection BP is used for

This medicine 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.

This medicine belongs to a group of antihistamines called phenothiazines (*fen-oh-THY-ah-zines*). It works by preventing the effects of histamine in the body.

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.

It is available only with a doctor's prescription.

Before you are given DBL™ Promethazine Hydrochloride Injection BP

When you must not be given it

You must not be given promethazine if you have an allergy to:

- any medicine containing promethazine hydrochloride
- any other phenothiazine-derivative antihistamines
- 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.

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.

You must not use this medicine after 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.

Before you are given it

Tell your doctor if you have any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- 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

Tell your doctor if you are pregnant or plan 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.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

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 breast-feeding.

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

Taking other medicines

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

Some medicines and promethazine may interfere with each other.

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
- central nervous system depressants (medicines that cause drowsiness or sleepiness) such as sedatives, tranquillisers, barbiturates, antihistamines, general anaesthetics and alcohol
- levodopa (medicine for Parkinson's disease)
- metrizamide, a contrast agent, injected into the spinal cord before an x-ray
- monoamine oxidase (MAO) inhibitors (medicine for depression)
- phenothiazines (medicine for thought disorder)

- quinidine, a medicine for rapid or irregular heartbeat
- medicines to treat cold and flu
- appetite suppressants
- tricyclic antidepressants (medicine for depression)

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.

Use in children

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 unusual excitement, nervousness, 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.

How DBL™ Promethazine Hydrochloride Injection BP is 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

Promethazine 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 (overdose)

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. However, if you experience severe side effects tell your doctor immediately, or contact the Poisons Information Centre for advice. (In Australia, call 13 11 26; in New Zealand call 0800 764 766.) or go to Accident and Emergency at the nearest hospital,

You may need urgent medical attention.

Symptoms of an overdose may include the side effects listed in the 'Side Effects' section but are usually of a more severe nature.

Ask your doctor or pharmacist if you have any concerns.

While you are being given DBL™ Promethazine Hydrochloride Injection BP

Things you must do

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.

Tell any other doctors, dentists, and pharmacists who treat you that you are being given this medicine.

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.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how promethazine affects you.

This medicine 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.

Be careful when drinking alcohol while being given this medicine.

If you drink alcohol, dizziness or drowsiness may be worse.

Use a sunscreen on exposed skin or remain covered if you go outdoors after being given promethazine.

This medicine may cause you to sunburn more easily.

Side Effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given promethazine.

This medicine helps most people, but it 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 attention if you get some of the side effects.

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

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

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

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- nausea and vomiting
- constipation or diarrhea
- loss of appetite
- sore throat and fever
- unusual bleeding or bruising
- unusual tiredness or weakness
- clumsiness or unsteadiness
- severe drowsiness
- severe dryness or mouth nose or throat
- feeling faint
- hallucinations
- restlessness
- shuffling walk

- trembling and shaking of hands
- difficulty in sleeping
- skin itch

Tell your doctor, nurse or pharmacist immediately if you notice any of the following:

- tremors or convulsions
- blurred vision
- confusion
- difficult or painful urination
- fast or slow heartbeat
- trouble breathing
- skin rash
- muscle spasms in the neck and back,
- jerky movements of the head and face
- flushing or redness of face
- unusual excitement, nervousness, restlessness or irritability
- ringing or buzzing in ears
- severe pain in the stomach with bloating, gut cramps and vomiting

These may be serious side effects. You may need urgent medical attention.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Some side effects may only be found when your doctor does tests from time to time to check your progress.

After being given DBL™ Promethazine Hydrochloride Injection BP

Storage

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.

Product description

What it looks like

DBL™ Promethazine Hydrochloride Injection BP is a clear, colourless solution.

Ingredients

DBL™ Promethazine Hydrochloride Injection BP contains 50 mg/ 2 mL of promethazine hydrochloride as the active ingredient.

It also contains:

- disodium edetate
- acetic acid
- sodium acetate
- sodium metabisulfite
- water for injections.

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

Sponsor

DBL™ Promethazine Hydrochloride Injection BP is supplied by:

Australian Sponsor:

Pfizer Australia Pty Ltd
Sydney NSW
Toll Free Number: 1800 675 229
www.pfizer.com.au

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