

# BLOOMS THE CHEMIST Promethazine 10 Allergy Relief and BLOOMS THE CHEMIST Promethazine 25 Allergy Relief

Active ingredient(s): *promethazine hydrochloride* (PRO-meth-ar-zine HIGH-dro (h)-CLOR-ride)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using BLOOMS THE CHEMIST Promethazine Allergy Relief. **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 BLOOMS THE CHEMIST Promethazine Allergy Relief**

Where to find information in this leaflet:

- [1. Why am I using BLOOMS THE CHEMIST Promethazine Allergy Relief?](#)
- [2. What should I know before I use BLOOMS THE CHEMIST Promethazine Allergy Relief?](#)
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## 1. Why am I using BLOOMS THE CHEMIST Promethazine Allergy Relief?

BLOOMS THE CHEMIST Promethazine Allergy Relief contains the active ingredient promethazine hydrochloride.

BLOOMS THE CHEMIST Promethazine Allergy Relief is an antihistamine used to treat a number of conditions:

- allergies - allergic contact dermatitis, hives, hayfever, bites and stings
- respiratory symptoms due to allergies - runny nose
- nausea and vomiting - motion sickness
- assists in the management of the symptoms of chicken pox and measles by acting as a sedative
- for short-term use for sedation on the advice of a pharmacist or doctor- do not use for more than 7-10 days

Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine. Histamine is produced by the body in response to foreign substances that the body is allergic to.

Your pharmacist or doctor may have recommended BLOOMS THE CHEMIST Promethazine Allergy Relief for another reason.

Ask your pharmacist or doctor if you have any questions about this medicine.

## 2. What should I know before I use BLOOMS THE CHEMIST Promethazine Allergy Relief?

### Warnings

**BLOOMS THE CHEMIST Promethazine Allergy Relief must not be used in children under 6 years of age, due to the potential for fatal respiratory depression, psychiatric and CNS events.**

**Do not use BLOOMS THE CHEMIST Promethazine Allergy Relief if:**

- you are allergic to promethazine hydrochloride, medicines of similar properties or belonging to the specific family of chemicals called phenothiazines, other phenothiazines or any of the ingredients listed at the end of this leaflet.

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

Some of the symptoms of an allergic reaction 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

If you take this medicine after the expiry date has passed, it may not work as well.

- **the packaging is torn or shows signs of tampering.**

**Any person who is unconscious or in a coma must not be treated with BLOOMS THE CHEMIST Promethazine Allergy Relief .**

**Do not give BLOOMS THE CHEMIST Promethazine Allergy Relief to newborn or premature babies.**

**Check with your doctor or pharmacist if you:**

- have allergies:
  - any other medicines
  - any other substances, such as food, preservatives or dyes
- have or have had any medical conditions, especially the following:
  - kidney or liver disease
  - Parkinson's disease
  - underactive thyroid gland (hypothyroidism)
  - tumour growing in adrenal glands (pheochromocytoma)
  - autoimmune disorder (myasthenia gravis)
  - epilepsy
  - cardiovascular disease/cardiac failure

- blood pressure problems
- low white blood cell count (agranulocytosis)
- bladder problems
- breathing problems
- glaucoma - an eye condition
- prostate problems
- stomach ulcer or blockage
- develop a fever or an infection to confirm if laboratory tests are required to check your blood count
- plan to have surgery
- take sedatives
- take any medicines for any other condition
- have any personal or family history of heart disease
- have an irregular heartbeat

If you experience an allergic reaction, seek medical help right away.

Caution must be exercised when using BLOOMS THE CHEMIST Promethazine Allergy Relief due to the risk of sedation.

If you experience fever, sore throat or any other infection, you should inform your doctor or pharmacist immediately and undergo a complete blood count. Treatment should be discontinued if any marked changes are observed in the blood count.

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 or pharmacist if you are a woman of childbearing age and not using effective contraception. Check with your doctor or pharmacist if you are pregnant, might become pregnant or think you may be pregnant.**

**Do not take BLOOMS THE CHEMIST Promethazine Allergy Relief if you are pregnant or plan to become pregnant.**

It may affect your developing baby if you take it during pregnancy. If there is a need to consider BLOOMS THE CHEMIST Promethazine Allergy Relief during your pregnancy, your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

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

**Do not take BLOOMS THE CHEMIST Promethazine Allergy Relief if you are breastfeeding or plan to breastfeed.**

It passes into the breast milk and there is a possibility that the baby may be affected.

### Use in children

- **Do not give BLOOMS THE CHEMIST Promethazine Allergy Relief to newborn or premature babies.**
- **BLOOMS THE CHEMIST Promethazine Allergy Relief must not be used in children under 6 years of age, due to the potential for fatal respiratory depression, psychiatric and CNS events.**

- **Because of the risk of choking, the tablets should be avoided in children who have difficulty swallowing tablets.**

### 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 BLOOMS THE CHEMIST Promethazine Allergy Relief and affect how it works.**

BLOOMS THE CHEMIST Promethazine Allergy Relief may increase the sedative effect of some medicines. These include:

- medicines used to treat depression, especially monoamine oxidase inhibitors and tricyclic antidepressants
- medicines used to help you sleep or relax (sedatives and hypnotics)
- opioid analgesics, medicines used to treat pain
- other antihistamines
- alcohol and alcohol containing medicines
- medicines for the treatment of irregular heartbeats (antiarrhythmics)
- medicines that help with your mood (antidepressants)
- medicines used to help with mental illness (antipsychotics)
- medicines to treat infections (antimicrobials)
- medicines used to treat nausea and vomiting like metoclopramide
- medicines used to relieve muscle spasm like carisoprodol and cyclobenzaprine
- medicines used for the treatment of epilepsy or seizures
- medicines used to treat acid indigestion such as magnesium, aluminium and calcium salts, oxides and hydroxides
- medicines used to smooth muscle contractions in the gastrointestinal tract (antispasmodics)

These medicines may be affected by BLOOMS THE CHEMIST Promethazine Allergy Relief or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BLOOMS THE CHEMIST Promethazine Allergy Relief.**

### 4. How do I use BLOOMS THE CHEMIST Promethazine Allergy Relief?

#### How much to take

- Follow the instructions provided with the medicine. If you do not understand the instructions on the carton or the label, ask your pharmacist or doctor for help.
- Follow all directions given to you by your pharmacist or doctor carefully.

They may differ from the information contained in this leaflet.

- Use this drug only as recommended.
- Do not exceed the recommended dosage. There have been case reports of promethazine abuse.
- BLOOMS THE CHEMIST Promethazine Allergy Relief tablets are recommended for adults and children over 6 years of age.
- BLOOMS THE CHEMIST Promethazine Allergy Relief tablets should not be given to children aged between 6 and 11 years of age, except on the advice of your doctor or pharmacist.
- **It is recommended that the lowest effective dose of BLOOMS THE CHEMIST Promethazine Allergy Relief be used in children 6 years of age or older.**

### Allergic Disorder

- Adults and children over 12 years of age: One to three 25mg tablets as a single dose at night, or one to two 10mg tablets, two to three times daily.
- Children 6-12 years: One to two 10mg tablets as a single dose at night, or one 10mg tablet, two to three times daily.

### Sedation

For short term use on the advice of a doctor or pharmacist. Do not take for more than 7 – 10 consecutive days.

- Adults and children over 12 years of age: One to three 25mg tablets as a single dose at night.
- Children 6-12 years: One to two 10mg tablets as a single dose at night.

### Travel Sickness

- Adults and children over 12 years of age: One 25mg tablet.
- Children 6-12 years: One 10mg tablet.

To be taken the night before travel and repeated after 6 to 8 hours on the following day if required.

### Nausea and Vomiting

- Adults and children over 12 years of age: One 25mg tablet every 4 to 6 hours to a maximum daily dose of four 25mg tablets (100 mg in total).
- Children 6-12 years: One 10mg tablet every 4 to 6 hours to a maximum daily dose of two 10mg tablets (20 mg in total).

### Use in Elderly

- If you are over 65 years of age, talk to your doctor or pharmacist about how much to take.
- Elderly patients are more likely to have side effects from taking these medicines.

### How to take BLOOMS THE CHEMIST Promethazine Allergy Relief

- Swallow BLOOMS THE CHEMIST Promethazine Allergy Relief whole with a full glass of water.

### How long to take

- BLOOMS THE CHEMIST Promethazine Allergy Relief should not usually be taken for more than 10 days in a row. If your symptoms persist, see your doctor or pharmacist for advice.

### If you forgot to take

- If you are taking BLOOMS THE CHEMIST Promethazine Allergy Relief for an allergic disorder and you forget to take your bedtime dose, you may need to take your dose in two or three smaller doses during the following day. Check with your doctor or pharmacist.
- If you are taking BLOOMS THE CHEMIST Promethazine Allergy Relief for travel sickness or nausea and vomiting, take your dose as soon as you remember.
- If you are taking BLOOMS THE CHEMIST Promethazine Allergy Relief for sedation, take your dose as soon as you remember. Be careful because you may still be affected in the morning.

**Do not take a double dose to make up for the dose that you missed. This may be harmful.**

If you are not sure what to do, ask your pharmacist or doctor.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

### If you use too much BLOOMS THE CHEMIST Promethazine Allergy Relief (overdose)

If you think that you have used too much BLOOMS THE CHEMIST Promethazine Allergy Relief, you may need urgent medical attention.

**You should immediately:**

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

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

**If you take too much BLOOMS THE CHEMIST Promethazine Allergy Relief, you may experience:**

#### Adults

- **drowsiness**
- **convulsions and/or tremors**
- **difficulty breathing**
- **unconsciousness**
- **acute anxiety**
- **hallucinations**
- **heart palpitations, chest pain and/or rapid pulse**
- **dizziness**
- **nausea**
- **cold sweats**

#### Children

- **over-excitement**
- **shaky and unsteady movements**
- **convulsions and/or tremors**
- **hallucinations**
- **difficulty breathing**

- unconsciousness
- high fever
- heart palpitations, chest pain and/or rapid pulse
- dizziness
- nausea
- cold sweats
- memory and thinking problems; difficulty with learning new things, concentrating, or making decisions

## 5. What should I know while using BLOOMS THE CHEMIST Promethazine Allergy Relief?

### Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using BLOOMS THE CHEMIST Promethazine Allergy Relief.

BLOOMS THE CHEMIST Promethazine Allergy Relief may cause skin to be more sensitive to the sun. You should protect your skin from sun or exposure to bright sunlight.

If you are about to be started on any new medicine, tell your pharmacist or doctor that you are taking BLOOMS THE CHEMIST Promethazine Allergy Relief .

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

If you become pregnant while you are taking this medicine, stop taking it and tell your doctor immediately.

Talk to your pharmacist or doctor if your symptoms do not improve.

Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine

### Things you should not do

- Do not give BLOOMS THE CHEMIST Promethazine Allergy Relief to anyone else, even if they have the same condition as you.
- Do not take BLOOMS THE CHEMIST Promethazine Allergy Relief to treat any other complaints unless your pharmacist or doctor tells you to.
- Do not take more than the recommended dose unless your pharmacist or doctor tells you to
- Do not take BLOOMS THE CHEMIST Promethazine Allergy Relief if you have jaundice.
- Do not take this medicine if you are receiving or have received high doses of other CNS depressant medications (for example, drugs that are used to treat anxiety and sleep disorders).
- Do not take this medicine if you have slowed breathing or heart rate of any cause.

### Things to be careful of

- BLOOMS THE CHEMIST Promethazine Allergy Relief is a known sedative and may cause drowsiness in some people.
- If you have a single dose at bedtime, you may still be affected in the morning.

- Children and the elderly are especially sensitive to the effects of antihistamines.

### Neuroleptic malignant syndrome

A very serious and sometimes deadly health problem called neuroleptic malignant syndrome (NMS) may happen. Stop treatment and call your doctor right away if you have high fever, muscle cramps or stiffness, dizziness, very bad headache, fast heartbeat, confusion, agitation, hallucinations, or are sweating a lot.

### Driving or using machines

BLOOMS THE CHEMIST Promethazine Allergy Relief can cause drowsiness, dizziness and blurred vision.

Make sure you know how you react to BLOOMS THE CHEMIST Promethazine Allergy Relief before you drive a car, operate machinery, or do anything else that could be dangerous if you experience drowsiness, dizziness and blurred vision. If this occurs do not drive or operate machinery.

Be careful before you drive or use any machines or tools until you know how BLOOMS THE CHEMIST Promethazine Allergy Relief affects you.

BLOOMS THE CHEMIST Promethazine Allergy Relief may affect your ability to drive a car or operate machinery or do anything else that could be dangerous if you are drowsy, dizzy or experience blurred vision. If this occurs do not drive or operate machinery.

### Drinking alcohol

**Tell your doctor or pharmacist if you drink alcohol.**

Do not drink alcohol while taking BLOOMS THE CHEMIST Promethazine Allergy Relief.

The sedation effects of alcohol may be increased.

### Looking after your medicine

- Keep your medicine in the original container until it is time to take it.
- If you take your medicine out of the pack it will not keep as well.
- Keep your tablets in a cool dry place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it**, in a locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe.

Do not use this medicine after the expiry date.

## 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.

### Less serious side effects

| Less serious side effects   | What to do  |
|---|---|
| <p><b>General</b></p> <ul style="list-style-type: none"> <li>• dry mouth, nose &amp; throat</li> </ul> <p><b>Nervous system-related</b></p> <ul style="list-style-type: none"> <li>• tiredness or sleepiness</li> <li>• headache</li> <li>• involuntary muscle movements (dystonia)</li> </ul> <p><b>Mental</b></p> <ul style="list-style-type: none"> <li>• nightmares in children</li> <li>• restlessness</li> <li>• confusion</li> <li>• anxiety</li> <li>• aggression</li> <li>• hallucination</li> </ul> <p><b>Gastrointestinal</b></p> <ul style="list-style-type: none"> <li>• stomach upset</li> <li>• loss of appetite</li> <li>• nausea or vomiting</li> <li>• diarrhoea or constipation</li> </ul> <p><b>Eye disorders</b></p> <ul style="list-style-type: none"> <li>• blurred vision</li> </ul> <p><b>Respiratory</b></p> <ul style="list-style-type: none"> <li>• congested nose</li> </ul> <p><b>Skin-related</b></p> <ul style="list-style-type: none"> <li>• increased sensitivity of the skin to sun</li> </ul> | <p><b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b></p> |

These are mild side effects of the medicine and are short lived.

### Serious/rare side effects

| Serious side effects   | What to do  |
|--|---|
| <p><b>General</b></p> <ul style="list-style-type: none"> <li>• fever</li> <li>• excessive sweating</li> <li>• dizziness</li> <li>• nausea</li> <li>• cold sweats</li> <li>• low blood pressure</li> <li>• shortness of breath</li> </ul> <p><b>Urinary</b></p> <ul style="list-style-type: none"> <li>• difficulty passing urine</li> </ul> <p><b>Heart</b></p> <ul style="list-style-type: none"> <li>• irregular heartbeat</li> <li>• very fast or forceful heartbeats (palpitations)</li> </ul> | <p><b>Call your doctor straight away if you notice any of these serious side effects.</b></p> |

|   |  |
|---|--|
| <ul style="list-style-type: none"> <li>• chest pain</li> <li>• rapid pulse</li> </ul> <p><b>Blood and Lymphatic System Disorders</b></p> <ul style="list-style-type: none"> <li>• eosinophilia which is an increase in the number of eosinophils (a type of white blood cells) found in the blood test. <ul style="list-style-type: none"> <li>• Thrombocytopenia which is a decrease in the number of platelets (cells in the blood that help with clotting) found in a blood test, which can lead to bleeding and bruising (thrombocytopenic purpura)</li> </ul> </li> </ul> <p><b>Allergy related</b></p> <ul style="list-style-type: none"> <li>• difficulty breathing</li> </ul> <p><b>Liver-related</b></p> <ul style="list-style-type: none"> <li>• jaundice - yellow tinge to skin or eyes</li> </ul> <p><b>Nervous system-related</b></p> <ul style="list-style-type: none"> <li>• tremors or convulsions</li> <li>• tinnitus - buzzing, hissing, ringing or other persistent noise in the ears</li> <li>• confusion</li> <li>• twitching or jerking muscles</li> <li>• dizziness, lightheadedness</li> <li>• severe headache</li> <li>• muscle cramps or stiffness</li> <li>• psychomotor hyperactivity</li> </ul> <p><b>Central nervous system-related</b></p> <ul style="list-style-type: none"> <li>• anxiety</li> <li>• seizures (fits)</li> <li>• hallucinations</li> <li>• agitation</li> <li>• nervousness and irritability</li> <li>• neuroleptic malignant syndrome (NMS) - see subheading "<i>Things to be careful of</i>"</li> <li>• severe uncontrollable muscular movements</li> </ul> |  |
|---|--|

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

### Very serious side effects

| Very serious side effects   | What to do  |
|---|---|
| <p><b>Allergy related</b></p> <ul style="list-style-type: none"> <li>• wheezing or difficulty breathing</li> <li>• swelling of the face, lips, tongue, or other parts of the body/severe allergic reaction where adrenaline is required for treatment (anaphylaxis)</li> <li>• skin rashes</li> </ul> | <p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> |

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

**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 <https://www.tga.gov.au/safety/reporting-problems>

By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

This medicine is available over-the-counter without a doctor's prescription.

### What BLOOMS THE CHEMIST Promethazine Allergy Relief contains

|   |   |
|---|---|
| <b>Active ingredient (main ingredient)</b>      | 10mg tablets - 10mg of promethazine hydrochloride per tablet<br>25mg tablets - 25mg of promethazine hydrochloride per tablet                                    |
| <b>Other ingredients (inactive ingredients)</b> | <ul style="list-style-type: none"><li>• magnesium stearate</li><li>• microcelac-100 (containing lactose monohydrate &amp; microcrystalline cellulose)</li></ul> |
| <b>Potential allergens</b>                      | Contains lactose  |

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

### What BLOOMS THE CHEMIST Promethazine Allergy Relief looks like

BLOOMS THE CHEMIST Promethazine Allergy Relief tablets are available in two strengths:

- 10mg tablets - round, white to off-white, flat faced, beveled- edged tablets, debossed 10 on one side and plain on the reverse side. (Aust R 342520).
- 25mg tablets - round, white to off-white, flat faced, beveled-edged tablets, debossed 25 on one side and plain on the reverse side. (Aust R 342521).

Both are available in blister packs of 50 tablets.

### Who distributes BLOOMS THE CHEMIST Promethazine Allergy Relief

Arrotex Pharmaceuticals Pty Ltd  
15-17 Chapel St  
Cremorne VIC 3121

Australia

[www.arrotex.com.au](http://www.arrotex.com.au)

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