# Promethazine hydrochloride 25 mg Film-coated Tablets

**Package leaflet:**
**Information for the user**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.
- The full name of this medicine is Promethazine hydrochloride 25 mg Film-coated Tablets but within the leaflet it will be referred to as Promethazine Tablets.

**What is in this leaflet:**


1. **What Promethazine Tablets are and what they are used for**
2. **What you need to know before you take Promethazine Tablets**
3. **How to take Promethazine Tablets**
4. **Possible side effects**
5. **How to store Promethazine Tablets**
6. **Contents of the pack and other information**


## 1 What Promethazine Tablets are and what they are used for

Promethazine Tablets contain a medicine called promethazine hydrochloride. This belongs to a group of medicines called phenothiazines. It works by blocking a natural substance (histamine) that your body makes during an allergic reaction. It also works directly on the brain to help you feel more relaxed.

Promethazine Tablets can be given to you either by a doctor or directly by a pharmacist depending on the condition you are being treated for.

Promethazine Tablets may be provided directly by a pharmacist for use in the following situations:

- to treat allergic conditions such as hay fever or rashes (like nettle rash or hives)
- to treat adults with difficulty sleeping (insomnia)
- to treat or stop you feeling sick (nausea) or being sick (vomiting) such as travel sickness.

Promethazine Tablets may also be given to you by a doctor. This can be for use in any of the above situations or for use in the following additional situation:

- as a sedative for children. This is a medicine given to reduce awareness or make you feel relaxed and at ease.

## 2 What you need to know before you take Promethazine Tablets

**Do not take this medicine and tell your doctor if:**

- you are allergic to promethazine hydrochloride or any of the other ingredients of this medicine (listed in section 6). The signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- you are taking a medicine for depression called a monoamine oxidase inhibitor (MAOI). Also, do not take Promethazine Tablets if you have stopped taking one of these MAOI medicines within the last 14 days. If you are not sure, ask your doctor or pharmacist (see "Other medicines and Promethazine Tablets" section below).
- the person is unconscious (in a coma) or suffers from severe dizziness, drowsiness or headache.

Do not give Promethazine Tablets to children younger than 5 years.
Other strengths and pharmaceutical forms of promethazine may be available for use in children aged 2 to 5 years.

**Warnings and precautions**
Talk to your doctor or pharmacist before taking Promethazine Tablets if you have:

- difficulty breathing, wheezing, tightness in the chest (asthma) or an infection in your lungs (bronchitis)
- epilepsy
- any serious heart problems
- liver or kidney problems
- a stomach blockage or difficulty passing water
- hearing problems
- increased pressure in the eye (narrow angle glaucoma)
- had something called Reye's Syndrome or possible Reye's Syndrome – signs include being sick and confused following a viral illness.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Promethazine Tablets.

Promethazine Tablets may occasionally cause a condition called neuroleptic malignant syndrome which is potentially life-threatening. If you notice symptoms such as high temperature, pale complexion, muscle stiffness or tremor, and changes in your mental state (such as confusion, irritability and extreme agitation), you should **stop taking these tablets and immediately inform your doctor**. See also section 4 'Possible side effects'.

**Other medicines and Promethazine Tablets**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

**Do not take this medicine, and tell your doctor, if you are taking or have taken the following in the last 2 weeks:**

- some medicines for depression called monoamine oxidase inhibitors (MAOIs). If you are not sure, ask your doctor or pharmacist.

**Tell your doctor or pharmacist if you are taking any of the following:**

- anticholinergic medicines – includes some medicines used for irritable bowel syndrome, asthma or weak bladder. These can increase the risk of dizziness, dry mouth and blurred eyesight
- medicines for depression (such as amitriptyline)
- medicines to help you to sleep or feel more relaxed (such as diazepam or zolpidem)
- medicines such as aspirin (for arthritis and pain in your joints). Promethazine Tablets may hide the side effects of these medicines.

**Promethazine Tablets with alcohol**
Do not drink alcohol while you are taking Promethazine Tablets. This is because it can affect the way the medicine works.

**Pregnancy and breast-feeding**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Promethazine Tablets should not be taken 2 weeks before birth.

You should not take Promethazine Tablets if you are breast-feeding. This is because small amounts may pass into mothers' milk. This can be harmful to your baby. If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine.

**Driving and using machines**
You may feel drowsy or sleepy after taking this medicine. If this happens, do not drive or use any tools or machines.

**Promethazine Tablets contains sodium**
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## 3 How to take Promethazine Tablets

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The amount you need to take depends on the reason you are taking Promethazine Tablets. The following information will help you to decide how much you need to take.

**Taking this medicine**
Take this medicine by mouth.
Do not take for longer than 7 days. If your symptoms worsen or do not improve after 7 days, talk to your doctor or pharmacist.
If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

The recommended dose is:
**For allergies (such as hay fever, rashes and hives)**
**Children 5-10 years:**
- 25 mg given at night
- **Do not** give more than 25 mg each day.

**Children over 10 years and adults (including the elderly):**
- Start with 25 mg taken at night
- This may be increased to a maximum of 25 mg twice a day if necessary.

**For treatment and prevention of feeling sick or being sick (such as travel sickness)**
**Children over 10 years and adults (including the elderly):**
- 25 mg to be taken the night before the journey
- This may be repeated after 6-8 hours if necessary.

**For treatment of adults with difficulty sleeping (insomnia)**
**Adults (including the elderly):**
- 25 mg or 50 mg taken at night.

**As a sedative for children (under the advice of a doctor only)**
Promethazine Tablets may also be used as a short term sedative. This will normally have been prescribed by a doctor. The information below is a guide to the doses recommended.
**Children 5-10 years:**
- 25 mg given at night.

**Children over 10 years:**
- 25 mg or 50 mg taken at night.

**Exposure to sunlight**
Promethazine Tablets can make your skin more sensitive to sunlight. Keep out of direct sunlight while taking this medicine.

**If you take more Promethazine Tablets than you should**
If you or your child takes more Promethazine Tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you or your child has taken. The following effects may happen:
**In children:** Excitation, moving unsteadily or stumbling, uncontrolled writhing movements especially of the hands or feet, hallucinations, fits (seizures), loss of consciousness, uneven heartbeat and breathing difficulties.
**In adults:** Feeling sleepy or drowsy, fits, loss of consciousness, uneven heartbeat and breathing difficulties.

**If you forget to take Promethazine Tablets**
Do not take a double dose to make up for a forgotten dose.
- If you are taking Promethazine Tablets for an allergic condition - take your medicine as soon as you remember, then carry on as before.
- If you are taking Promethazine Tablets for sedation or sleeping problems - miss that dose and take the next evening's dose as usual.

**Tests**
Taking Promethazine Tablets may affect the results of certain tests. These include some pregnancy tests and skin tests. Promethazine Tablets should not be taken for at least 3 days before the start of a skin test.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Stop taking Promethazine Tablets and see a doctor or go to a hospital straight away if you notice any of the following side effects:**
- an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- liver problems that may cause the eyes or skin to go yellow (jaundice)
- muscle stiffness or shaking

- being unable to control some muscles in your head or face
- you notice unusual movements of the tongue, facial muscle spasms, rolling eyes and trembling
- very fast, uneven or forceful heartbeat (palpitations)
- tiredness which lasts for a long time. This may be due to a blood problem called anaemia.
- over-active behaviour in children
- a combination of symptoms (known as 'neuroleptic malignant syndrome') including high temperature, pale complexion, muscle stiffness or tremor, and changes in your mental state (such as confusion, irritability and extreme agitation). See also section 2 'Warnings and precautions'.

**Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days. Also tell them if you notice any side effects not listed in this leaflet.**

- dry mouth, blurred vision or you cannot pass water (urine)
- feeling drowsy or sleepy, tiredness, disorientation, having nightmares, headaches, feeling restless
- loss of appetite (anorexia), indigestion
- feeling dizzy, lightheaded, faint (hypotension)
- feeling confused, especially in elderly people
- being more sensitive to the sun than usual. If this happens keep out of direct sunlight and do not use sun lamps.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

## 5 How to store Promethazine Tablets

**Keep this medicine out of the sight and reach of children.**

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP.

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6 Contents of the pack and other information

**What Promethazine Tablets contain**

- The active substance is promethazine hydrochloride.
- The other ingredient(s) are:
  **Tablet core:** microcrystalline cellulose, calcium hydrogen phosphate dihydrate, sodium starch glycolate (Type A), stearic acid, magnesium stearate.
  **Tablet coating:** hypromellose (E464), macrogol 8000 (E1521), titanium dioxide (E171), talc.

**What Promethazine Tablets look like and contents of the pack**

Promethazine 25 mg Film-coated Tablets are white oval shaped, 9.8 x 6.2mm biconvex marked with "C25" on one side and plain on the other side.

**Pack sizes**

Blisters: 56 film-coated tablets.

**Marketing Authorisation Holder**

TEVA UK Limited, Eastbourne, BN22 9AG, United Kingdom

**Manufacturer**

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