

Package leaflet: Information for the patient  
**Promethazine Hydrochloride 10 mg Film-coated Tablets**

promethazine hydrochloride

The name of this medicine is Promethazine Hydrochloride 10 mg Film-coated Tablets, but it will be referred to as Promethazine Hydrochloride Tablets throughout this leaflet.

**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

**What is in this leaflet**

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

Pharmcode

**1. What Promethazine Hydrochloride Tablets are and what they are used for**

Promethazine Hydrochloride Tablets contain the active substance 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 Hydrochloride Tablets are used:

- In the short term, to treat adults with difficulty sleeping (insomnia)
- To treat allergic conditions such as hay fever or rashes (like nettle rash or hives)
- To treat or stop you feeling sick (nausea) or being sick (vomiting) in conditions such as travel sickness
- In the short term, as a sedative for children aged 5 years and above

**2. What you need to know before you take Promethazine Hydrochloride Tablets**

**Do not take Promethazine Hydrochloride Tablets**

- If the person taking the medicine is under 5 years of age
- If you are allergic (hypersensitive) to promethazine hydrochloride or any of the other ingredients in Promethazine Hydrochloride Tablets (listed in section 6 below). The signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- If you are taking a medicine for depression called a monoamine oxidase inhibitor (MAOI). Also do not take Promethazine Hydrochloride 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 Hydrochloride Tablets” section below)
- If the person is unconscious (in a coma) or suffers from severe dizziness, drowsiness or headaches

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Promethazine Hydrochloride Tablets.

**Warnings and precautions**

**Talk to your doctor, pharmacist before taking Promethazine Hydrochloride Tablets**

- If you have difficulty breathing, wheezing, tightness in the chest (asthma) or an infection in your lungs (bronchitis)
- If you have epilepsy
- If you have any serious heart problems
- If you have any personal or family history of heart disease
- If you have irregular heartbeat
- If you have liver or kidney problems
- If you have a stomach blockage or difficulty passing water (urine)
- If you have hearing problems
- If you have increased pressure in the eye (narrow angle glaucoma)
- If you have had something called Reye’s Syndrome or possible Reye’s Syndrome, signs include being sick and confused following a viral illness

**Exposure to sunlight**

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

**Tests**

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

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

**Other medicines and Promethazine Hydrochloride Tablets**

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you can buy without a prescription, including herbal medicines. This is because Promethazine Hydrochloride Tablets can affect the way some medicines work. Also, some medicines can affect the way Promethazine Hydrochloride Tablets work.

**In particular, 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 if you have taken these, ask your doctor or pharmacist

**Also tell your doctor or pharmacist if you are taking, have recently taken or might take 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 mental health problems (antipsychotics such as haloperidol and quetiapine) or depression (antidepressants such as amitriptyline and citalopram)
  - 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 Hydrochloride Tablets may hide the side effects of these medicines
  - Medicines for the treatment of irregular heartbeats (antiarrhythmics such as quinidine and amiodarone).
  - Antimicrobials (such as erythromycin and levofloxacin) for the treatment of infections.

**Promethazine Hydrochloride Tablets with food and drink/alcohol**

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

**Pregnancy and breast-feeding**

Talk to your doctor or pharmacist before taking this medicine if you are pregnant, think you may be pregnant or are planning to have a baby. Promethazine Hydrochloride Tablets should not be taken 2 weeks before birth.

You should not take Promethazine Hydrochloride Tablets if you are breast-feeding. This is because small amounts may pass into the mothers’ breastmilk. 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 or in the morning after taking this medicine. If this happens, do not drive or use any tools or machines.

**Promethazine Hydrochloride Tablets contain lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**3. How to take Promethazine Hydrochloride Tablets**

Always use 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 Hydrochloride 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

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50mm

6mm

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3mm

6mm

- Use this medicine only as recommended. Do not exceed the recommended dose.
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

#### How much to take

The recommended dose is:

#### For allergies (such as hay fever, rashes and hives)

##### Children 2-5 years:

- The liquid form of promethazine hydrochloride should be given in this age group.

##### Children 5-10 years:

- A single dose of either one or two tablets (10 mg or 20 mg) given at night or one tablet (10 mg) given twice a day
- DO NOT give more than two tablets (20 mg) each day

##### Children over 10 years and adults (including the elderly):

- Start with one tablet (10 mg) twice a day
- This may be increased to a maximum of two tablets (20 mg) three times a day

#### For treatment and prevention of feeling sick or being sick (such as travel sickness)

##### Children 2-5 years:

- The liquid form of promethazine hydrochloride should be given in this age group.

##### Children 5-10 years:

- A single tablet to be taken the night before the journey
- This may be repeated after 6-8 hours if necessary

##### Children over 10 years and adults (including the elderly):

- Two tablets (20 mg) to be taken the night before the journey
- This may be repeated after 6-8 hours if necessary

#### As a short term paediatric sedative and for short term treatment of insomnia in adults

##### Children 2-5 years:

- The liquid form of promethazine hydrochloride should be given in this age group.

##### Children 5-10 years:

- Two tablets (20 mg) given as a single dose at night time

##### Children over 10 years and adults (including the elderly):

- Two to five tablets (20 mg to 50 mg) as a single dose at night time

#### If you take more Promethazine Hydrochloride Tablets than you should

If you or your child take more Promethazine Hydrochloride 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 have 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 (seizures), loss of consciousness, uneven heartbeat and breathing difficulties.

#### If you forget to take Promethazine Hydrochloride Tablets

Do not take a double dose to make up for a forgotten dose

- If you are taking Promethazine Hydrochloride Tablets for an allergic condition - take your medicine as soon as you remember, then carry on as before
- If you are taking Promethazine Hydrochloride Tablets for sedation or sleeping problems - miss that dose and take the next evening's dose as usual

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

#### 4. Possible side effects

Like all medicines, Promethazine Hydrochloride Tablets can cause side effects, although not everybody gets them.

**Stop taking Promethazine Hydrochloride 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
- Unusual movements of the tongue, facial muscle spasms or being unable to control some muscles in your face, rolling eyes and trembling
- Very fast, irregular, uneven or forceful heartbeat (palpitations)
- General weakness, more frequent infections (particularly throat infection) and fever due to changes in the blood (agranulocytosis)
- Tiredness which lasts for a long time. This may be due to a blood problem called anaemia
- Overactive behaviour in children

**Tell your doctor or pharmacist if any of the following side effects get serious or last 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 or irritated stomach
- 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
- Unpleasant sensation or an overwhelming urge to move the legs (also called Restless Legs Syndrome)

#### 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 MHRA Yellow Card Scheme website: [www.mhra.gov.uk/yellowcard](http://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 Hydrochloride Tablets

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

Do not use Promethazine Hydrochloride Tablets after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month. If your tablets become discoloured or show any other sign of deterioration, please contact your doctor or pharmacist before taking your medicine.

Store below 30°C.

Store in the original package in order to protect from light.

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 to protect the environment.

#### 6. Contents of the pack and other information

##### What Promethazine Hydrochloride Tablets contain

- Each tablet contains 10 mg of the active substance, promethazine hydrochloride
- The other ingredients are lactose, maize starch, povidone, magnesium stearate, Opadry white (contains titanium dioxide - E171, hypromellose - E464 and macrogol/polyethylene glycol - E1521)

##### What Promethazine Hydrochloride Tablets look like and contents of the pack

White coloured, round, biconvex, bevelled edge film coated tablets, debossed with 'L10' on one side and plain on the other side.

Promethazine Hydrochloride 10 mg tablets are provided in Aluminium-PVC/PVDC blister packs of 28, 56, 84 and 100 tablets.

Not all pack sizes may be marketed.

##### Marketing Authorisation Holder and Manufacturer

Key Pharmaceuticals Ltd.  
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PE28 3JB, UK

**This leaflet was last revised in May 2024.**

Pharmacode

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