

# Package leaflet: Information for the user

## Promethazine hydrochloride

### 10 mg film-coated tablets

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

#### 1. What Promethazine is and what it is used for

The name of your medicine is Promethazine hydrochloride 10mg film-coated tablets (called Promethazine in the leaflet). 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 is used to treat the following conditions:

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

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

##### Do not take Promethazine 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.
- the person taking this medicine is under 5 years of age.
- you are taking a medicine for depression called a monoamine oxidase inhibitor (MAOI) or you have stopped taking one of these MAOI medicines within the last 14 days (See "Other medicines and Promethazine" section below). If you are not sure, ask your doctor or pharmacist.
- the person taking this medicine is unconscious (in a coma) or suffers from severe dizziness, drowsiness or headache.

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

##### Warnings and precautions for use

Check with your doctor or nurse before having Promethazine if you:

- have difficulty breathing, wheezing, tightness in the chest (asthma) or an infection in your lungs (bronchitis).
- have epilepsy.
- experience an allergic reaction (see section Side Effects), seek medical help right away.
- have any serious heart problems.
- have any personal or family history of heart disease.
- have an irregular heartbeat.
- develop a fever or an infection. Talk to your doctor immediately as laboratory tests to check your blood count may be required.
- have liver or kidney problems.
- have a stomach blockage or difficulty in passing water.
- have hearing problems.
- have increased pressure in the eye (narrow angle glaucoma).
- have suffered from Reye's Syndrome or you have signs of Reye's Syndrome, such as being sick and confused after 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.

##### Exposure to sunlight

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

##### Tests

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

##### Other medicines and Promethazine

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

##### 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.

##### Also tell your doctor or pharmacist if you are taking, have recently taken, or might take any of the following:

- anticholinergic medicines, this 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 sleep or feel more relaxed (such as diazepam or zolpidem).
- medicines such as aspirin (for arthritis and pain in your joints). Promethazine may hide the side effects of these medicines.
- medicines for the treatment of irregular heartbeats (antiarrhythmics such as quinidine and amiodarone).
- medicines that can affect your heart rhythm.
- antidepressants (such as amitriptyline and citalopram).
- antipsychotics (such as haloperidol and quetiapine).
- medicines for the treatment of epilepsy or seizures.
- antimicrobials (such as erythromycin and levofloxacin).

##### Promethazine with food and drink

Do not drink alcohol whilst taking Promethazine. This is because it can affect the way the medicine works.

##### Pregnancy and breast-feeding

###### Pregnancy

Use of Promethazine Tablets is not recommended in pregnancy. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Promethazine should not be taken 2 weeks before birth.

###### Breast-feeding

You should not take Promethazine if you are breast-feeding. This is because small amounts may pass into the mother's milk. This could 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, dizzy or sleepy or have blurred vision after taking this medicine or the morning after taking this medicine. If this happens, do not drive or use any tools or machines. You should not drive a vehicle or operate machinery until you know how Promethazine Tablets affect you.

##### Promethazine 10 mg film-coated tablets contain 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

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. 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

### How much to take

The recommended dose is:

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

**Children 2-5 years:** a liquid form of this medicine should be used.

**Children 5-10 years:** a single dose of either one or two tablets (10mg or 20mg) given at night or one tablet (10mg) given twice a day • DO NOT give more than two tablets (20mg) each day.

**Children over 10 years and adults (including the elderly):** Start with one tablet (10mg) twice a day This may be increased to a maximum of two tablets (20mg) three times a day.

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

**Children 2-5 years:** a liquid form of this medicine should be used.

**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 (20mg) 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:** a liquid form of this medicine should be used.

**Children 5-10 years:** two tablets (20mg) given as a single dose at night time

**Children over 10 years and adults (including the elderly):** two to five tablets (20mg to 50mg) as a single dose at night time.

Use this medicine only as recommended.

Do not exceed the recommended dose.

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

If you or your child takes more Promethazine 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 heart beat and breathing difficulties.

**In adults:** Feeling sleepy or drowsy, fits, loss of consciousness, uneven heart beat and breathing difficulties.

#### If you forget to take Promethazine

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

- if you are taking Promethazine for an allergic condition - take your medicine as soon as you remember, then carry on as before
- if you are taking Promethazine 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, this medicine can cause side effects, although not everybody gets them.

#### Stop taking Promethazine and see a doctor or go to a hospital straight away if you notice any of the following side effects:

- Allergic reactions (that can occur either immediately or within several days of drug administration) that may be life-threatening. Symptoms may include rash, itching, difficulty breathing, shortness of breath, swelling of the face, lips, throat, or tongue, cold, clammy skin, palpitations, dizziness, weakness or fainting
- liver problems that may cause the eyes or skin to go yellow (jaundice) and darkening of urine
- 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)
- irregular heartbeat
- 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
- over-active behaviour in children.

- Eosinophilia which is an increase in the number of eosinophils (a type of white blood cell). Eosinophilia will be detected by a blood test.
- 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).
- A feeling of aggression, hallucinations and hyperactivity in children

#### 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, 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)

Frequency not known (cannot be estimated from the available data):

- Abnormal electrical activity of the heart that affects its rhythm, including life-threatening rhythm disturbance
- A serious reaction with fever, rigid muscles, changing blood pressure and coma (neuroleptic malignant syndrome)
- Low levels of blood platelets (which can lead to bleeding and bruising)
- Restlessness
- Hallucinations
- Aggression

#### 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 at: [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

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister after EXP. The expiry date refers to the last date of that month.
- This medicinal product does not require any special storage condition.
- 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 10 mg film-coated tablets contains

- Each tablet contains 10 mg of the active substance, promethazine hydrochloride.
  - The other ingredients are: calcium hydrogen phosphate dihydrate, cellulose microcrystalline type 101, sodium starch glycolate (Type A), stearic acid, magnesium stearate.
- Tablet coating: Opadry white 03A28437 containing: hypromellose type 2910 (E464), titanium dioxide (E171).

#### What Promethazine 10 mg film-coated tablets look like and contents of the pack

10 mg Promethazine tablets are white to off-white coloured round shaped, biconvex film coated tablet debossed with "P10" on one side and plain on other side, 6.00 mm ( $\pm$  0.30 mm) in diameter.

Packaged in PVC/PVDC/Al blister.

Pack size 56 tablets

#### Marketing Authorisation Holder and Manufacturer

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#### Other formats

To request a copy of this leaflet in Braille, large print or audio, please call 01926 482511.

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