

Package leaflet: Information for the patient

**Promethazine Hydrochloride 25mg Film-coated Tablets**

(Promethazine hydrochloride)

**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 name of your medicine is Promethazine Hydrochloride 25 mg Film-coated Tablets (referred to as Promethazine Hydrochloride Tablets throughout this leaflet).

**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

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

Promethazine Hydrochloride 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.

**What Promethazine Hydrochloride Tablets are used for**

Promethazine Hydrochloride Tablets are 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 or stop you feeling sick (nausea) or being sick (vomiting) such as travel sickness
- For short term use: as a sedative for children aged 6 years and above

**2. What you need to know before you take Promethazine Hydrochloride Tablets****Do not take this medicine if:**

- The person taking the medicine (as tablets) is under 6 years of age.
- You are allergic (hypersensitive) to promethazine hydrochloride or any of the other ingredients of 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.
- 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 “Taking other medicines” section below).
- The person is unconscious (in a coma) or suffers from severe dizziness, drowsiness or headache.

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

**Warnings and precautions****Check with your doctor or pharmacist before taking this medicine if**

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

**Children and adolescents**

Do not use in children less than 6 years of age. Because of the risk of choking, the tablets should be avoided in children who have difficulty swallowing tablets.

**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 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 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.

**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 – 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).
- Medicines for the treatment of epilepsy or seizures. • Medicines that can affect your heart rhythm
- Antimicrobials (such as erythromycin and levofloxacin) for the treatment of infections.

**Promethazine Hydrochloride Tablets with 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**

Use of Promethazine Hydrochloride Tablets is not recommended during pregnancy. Talk to your doctor or pharmacist before taking this medicine if you are a woman of childbearing age and not using effective contraception, or if you are pregnant, think you may be pregnant, or might become pregnant. Promethazine Hydrochloride Tablets should not be taken 2 weeks before child birth.

Do not take Promethazine Hydrochloride 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 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 Hydrochloride Tablets affect you.

**Promethazine Hydrochloride Tablets contains lactose:**

This is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

**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.
- 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 6-10 years:**

- A single tablet (25mg) given at night • DO NOT give more than 25mg each day

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

- Start with one tablet (25mg) taken at night
- This may be increased to a maximum of one tablet (25mg) twice a day if necessary

**For treatment and prevention of feeling sick or being sick (such as travel sickness)****Children 6-10 years:**

- Other forms of this medicine may be suitable for this age group ask your doctor or pharmacist.

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

- A single tablet (25 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 6-10 years:**

- A single tablet (25mg) given at night

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

- One or two tablets (25mg-50mg) taken at night

Use this medicine only as recommended. Do not exceed the recommended dose.

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

If you or your child takes 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 and show this to the doctor. This is so the doctor knows what you or your child has taken.

Signs of an overdose include:

**In adults:** Feeling sleepy or drowsy, fits (seizures or convulsions), coma, loss of consciousness, uneven heartbeat and breathing difficulties.

**In children:** Excitation, moving unsteadily or stumbling, uncontrolled writhing movements especially of the hands or feet and hallucinations, limited ability to learn and impairments in thinking, learning, or memory.

**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. 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

**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** (that can occur either immediately or within several days of drug administration) that may be life-threatening. The signs may include: a rash, itching, difficulty breathing, shortness of breath, swelling of your lips, face, 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
- 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)
- 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).
- Tiredness which lasts for a long time. This may be due to a blood problem called anaemia.
- A feeling of aggression, hallucinations, and over-active behavior 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 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 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 Hydrochloride Tablets**

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

Do not use Promethazine Hydrochloride Tablets after EXP. The expiry date stated on the carton and blister strip.

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 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 contains**

- Each tablet contains 25mg of the active substance, Promethazine Hydrochloride.
- The other ingredients are lactose, maize starch, povidone K30, magnesium stearate, Opadry Blue (contains titanium dioxide (E171), hypromellose (E464) and indigo carmine aluminium lake blue (E132) and Macrogol/Polyethylene glycol (E1521).


**What Promethazine Hydrochloride Tablets looks like and contents of the pack**

Round, pale blue colored, biconvex, bevelled edge film coated tablets.

Promethazine Hydrochloride 25 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:**

 **NOUMED LIFE SCIENCES LIMITED**  
Noumed House, Shoppenhangers Road,  
Maidenhead, Berkshire, SL6 2RB, UK

This leaflet was last revised in **November 2025**.

**Other sources of information:**

**To listen to or request a copy of this leaflet in braille, large print or audio please call, (UK only).**

**Please be ready to give the following information:**

**Product name: Promethazine hydrochloride 25 mg Tablets**

**Reference number: PL 44041/0171**

NOTE: pharmacode positioning  
is subject to change

**Font Type &  
Size**

**Main:**  
Times New Roman 11.5pts

**Body:**  
Times New Roman 9pts

DS rev v3 13.02.2025

<b>Signature of Author:</b>					
<b>Signature of RA:</b>					
				<b>Title: Art Work Approval Form</b>	
Product	Promethazine Hydrochloride Tablets - 25 mg - PIL		Specification:		
Customer	NOUMED LIFE SCIENCES LIMITED, UK				
Reason for Issue	Content update		Colours:	<b>Black</b>	
PL No.	44041/0171	Pharmacode No.	Dimensions:	160 x 440 (mm)	
	Item Code	LPRO05/05	Layout No.:		
				No. of Folds (only for PIL)	

Package leaflet: Information for the patient  
**Promethazine Hydrochloride 25mg Film-coated Tablets**  
(Promethazine hydrochloride)

**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 name of your medicine is Promethazine Hydrochloride 25 mg Film-coated Tablets (referred to as Promethazine Hydrochloride Tablets throughout this leaflet).

**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 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.

**What Promethazine Hydrochloride Tablets are used for**

Promethazine Hydrochloride Tablets are 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 or stop you feeling sick (nausea) or being sick (vomiting) such as travel sickness
- For short term use: as a sedative for children aged 6 years and above

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

**Do not take this medicine if:**

- The person taking the medicine (as tablets) is under 6 years of age.
- You are allergic (hypersensitive) to promethazine hydrochloride or any of the other ingredients of 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.
- 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 “Taking other medicines” section below).
- The person is unconscious (in a coma) or suffers from severe dizziness, drowsiness or headache.

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

**Warnings and precautions**

**Check with your doctor or pharmacist before taking this medicine if**

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

**Children and adolescents**

Do not use in children less than 6 years of age. Because of the risk of choking, the tablets should be avoided in children who have difficulty swallowing 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 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.

**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 – 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).
- Medicines for the treatment of epilepsy or seizures
- Antimicrobials (such as erythromycin and levofloxacin) for the treatment of infections
- Medicines that can affect your heart rhythm.

**Promethazine Hydrochloride Tablets with 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**

Use of Promethazine Hydrochloride Tablets is not recommended during pregnancy. Talk to your doctor or pharmacist before taking this medicine if you are a woman of childbearing age and not using effective contraception, or if you are pregnant, think you may be pregnant, or might become pregnant. Promethazine Hydrochloride Tablets should not be taken 2 weeks before child birth.

Do not take Promethazine Hydrochloride 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 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 Hydrochloride Tablets affect you.

**Promethazine Hydrochloride Tablets contains lactose:**

This is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

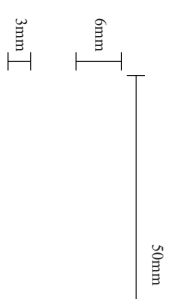
**3. How to take Promethazine Hydrochloride Tablets**

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.

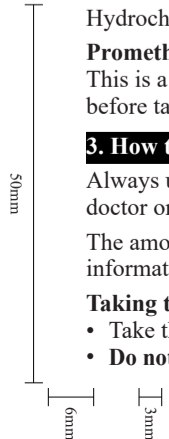
The amount you need to take depends on the reason you are taking Promethazine Hydrochloride Tablets. The following information will help you to decide how much you need to take

**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.



170x440mm



50mm

6mm 3mm

- 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 6-10 years:**

- A single tablet (25mg) given at night
- DO NOT give more than 25mg each day

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

- Start with one tablet (25mg) taken at night
- This may be increased to a maximum of one tablet (25mg) twice a day if necessary

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

**Children 6-10 years:**

Other forms of this medicine may be suitable for this age group; ask your doctor or pharmacist.

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

- A single tablet (25 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 6-10 years:**

- A single tablet (25mg) given at night

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

- One or two tablets (25mg-50mg) taken at night

Use this medicine only as recommended. Do not exceed the recommended dose.

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

If you or your child takes 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 and show this to the doctor. This is so the doctor knows what you or your child has taken.

Signs of an overdose include:

**In adults:** Feeling sleepy or drowsy, fits (seizures or convulsions, coma, loss of consciousness, uneven heartbeat and breathing difficulties.

**In children:** Excitation, moving unsteadily or stumbling, uncontrolled writhing movements especially of the hands or feet and hallucinations, limited ability to learn and impairments in thinking, learning, or memory.

**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.

*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

**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** (that can occur either immediately or within several days of drug administration) that may be life-threatening. The signs may include: a rash, itching, difficulty breathing, shortness of breath, swelling of your lips, face, 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
- 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)
- 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).
- Tiredness which lasts for a long time. This may be due to a blood problem called anaemia.
- A feeling of aggression, hallucinations, and over-active behavior 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 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 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 Hydrochloride Tablets**

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

Do not use Promethazine Hydrochloride Tablets after EXP. The expiry date stated on the carton and blister strip. 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 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 contains**

- Each tablet contains 25mg of the active substance, Promethazine Hydrochloride.
- The other ingredients are lactose, maize starch, povidone K30, magnesium stearate, Opadry Blue (contains titanium dioxide (E171), hypromellose (E464) and indigo carmine aluminium lake blue (E132) and Macrogol/Polyethylene glycol (E1521).


**What Promethazine Hydrochloride Tablets looks like and contents of the pack**

Round, pale blue colored, biconvex, bevelled edge film coated tablets.

Promethazine Hydrochloride 25 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:**

 **NOUMED LIFE SCIENCES LIMITED**  
Noumed House, Shoppenhangers Road,  
Maidenhead, Berkshire, SL6 2RB, UK

This leaflet was last revised in **November 2025**.

**Other sources of information:**

**To listen to or request a copy of this leaflet in braille, large print or audio please call, (UK only). Please be ready to give the following information:**

**Product name: Promethazine hydrochloride 25 mg Tablets**

**Reference number: PL 44041/0171**

Pharmacode

LPRO01/04

3mm 6mm

50mm

170x440mm

NOTE: pharmacode positioning  
is subject to change

**COLOURS**

 **Black**

**Font Type &  
Size**

**Main:**  
Times New Roman 11.5pts

**Body:**  
Times New Roman 9pts

<b>Signature of Author:</b>							
<b>Signature of RA:</b>							
				<b>Title: Art Work Approval Form</b>			
Product	Promethazine Hydrochloride Tablets - 25 mg - PIL			Specification:			
Customer	NOUMED LIFE SCIENCES LIMITED, UK						
Reason for Issue	Content update			Colours:	<b>Black</b>		
				Dimensions:	170 x 440 (mm)		
PL No.	44041/0171	Pharmacode No.		No. of Folds (only for PIL)			
Item Code	LPRO01/04	Layout No.:	DS v4 10.02.2025				