

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Phenergan 25 mg Tablets

promethazine hydrochloride

SANOFI 

 Is this leaflet hard to see or read?
Phone 0845 372 7101 for help

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Phenergan Tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- You must contact a doctor if your symptoms worsen or do not improve after 7 days
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

In this leaflet:

1. What Phenergan Tablets are and what they are used for
2. Before you take Phenergan Tablets
3. How to take Phenergan Tablets
4. Possible side effects
5. How to store Phenergan Tablets
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1. What Phenergan Tablets are and what they are used for



Phenergan 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 Phenergan Tablets are used for

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

Phenergan 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

Phenergan 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 situations:

- To help you feel more relaxed before an operation
- If you are having difficulty sleeping
- As a sedative for both adults and children. This is a medicine given to reduce awareness or make you feel relaxed and at ease

2. Before you take Phenergan Tablets

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

- × The person taking the medicine is under 2 years of age
- × You are allergic (hypersensitive) to promethazine hydrochloride or any of the other ingredients of Phenergan 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 Phenergan 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

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 Phenergan Tablets.



Take special care with Phenergan Tablets

Check with your doctor or pharmacist before taking your medicine if

- ▲ You have difficulty breathing, wheezing, tightness in the chest (asthma) or an infection in your lungs (bronchitis)
- ▲ You have epilepsy
- ▲ You have any serious heart problems
- ▲ You have liver or kidney problems
- ▲ You have a stomach blockage or difficulty passing water
- ▲ 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

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



Taking other medicines

Please 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 Phenergan Tablets can affect the way some medicines work. Also some medicines can affect the way Phenergan 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

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). Phenergan Tablets may hide the side effects of these medicines

Taking Phenergan Tablets with food and drink

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

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant. Phenergan Tablets should not be taken 2 weeks before birth.

You should not take Phenergan 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.

Important information about some of the ingredients of Phenergan Tablets

This medicine contains:

- Lactose. This is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine

3. How to take Phenergan Tablets

The amount you need to take depends on the reason you are taking Phenergan Tablets. The following information will help you to decide how much you need to take. You should check with your doctor or pharmacist if you are not sure.

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 usual dose is:

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

Children 2-5 years:

- Phenergan Elixir should be given in this age group

Children 5-10 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 2-5 years:

- Phenergan Elixir should be given in this age group

Children 5-10 years:

- Phenergan Elixir or Phenergan 10mg Tablets should be given in this age group

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 sedative (under the advice of a doctor only)

Phenergan 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 2-5 years:

- Phenergan Elixir should be given in this age group

Children 5-10 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

Exposure to sunlight

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

If you take more Phenergan Tablets than you should

If you or your child takes more Phenergan 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 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 Phenergan Tablets

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

- If you are taking Phenergan Tablets for an allergic condition - take your medicine as soon as you remember, then carry on as before
- If you are taking Phenergan 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.

Tests

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

4. Possible side effects

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

Stop taking Phenergan 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

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.

United Kingdom

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

Malta

ADR Reporting, The Medicines Authority, Post-Licensing Directorate, 203 Level 3, Rue D'Argens, GŻR-1368 Gżira
 Website: www.medicinesauthority.gov.mt
 e-mail: postlicensing.medicinesauthority@gov.mt

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

5. How to store Phenergan Tablets

- Keep out of the reach and sight of children
- Do not take Phenergan Tablets after the expiry date which is stated on the carton and blister pack after EXP. The expiry date refers to the last day of that month
- Store below 30°C
- Store in the original carton in order to protect from light

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Phenergan Tablets contains.

- Each tablet contains 25mg of the active substance, promethazine hydrochloride. The other ingredients are lactose, maize starch, povidone, magnesium stearate, polyethylene glycol, Opaspray (contains titanium dioxide-E171, hypromellose-E464 and indigo carmine aluminium lake blue-E132) and hypromellose

What Phenergan Tablets look like and contents of the pack

A pale blue film coated tablet marked PN 25 on one side. The tablets are available in blister packs of 56.

Marketing Authorisation Holder and Manufacturer

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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