

Package leaflet: Information for the user

Phenergan® 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.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- 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.

In this leaflet:

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

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

- 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.
- As a sedative. 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 Phenergan Tablets

Do not take this medicine and tell your doctor if:

- The person taking the medicine is under 2 years of age because of the potential for serious breathing difficulties which may be fatal.
- 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 use if you or anyone in your family are born with or have had episodes with prolonged heart rhythm identified in the electrocardiogram and known as “Long QT syndrome”, or a history of serious heart rhythm disturbances known as “ventricular cardiac arrhythmia” or “Torsade de Pointes ventricular arrhythmia”, which are often presenting with syncope.

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.

Warnings and precautions

Use this drug only as recommended. Do not exceed the recommended dose. There have been case reports of promethazine abuse.

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.
- You have any personal or family history of heart disease
- You have irregular heartbeat

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

Children under 6 years of age

Phenergan Tablets must not be given to children under 2 years of age because of the potential for serious breathing difficulties which may be fatal.

Phenergan Tablets are not recommended in children 2 to 5 years of age due to the potential for psychiatric and nervous system adverse effects (see section 4).

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 mask the side effects of these medicines.
- Medicines for the treatment of irregular heartbeats (antiarrhythmics)
- Antidepressants
- Antipsychotics
- Antimicrobials

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

Phenergan Tablets should not be taken during pregnancy or when breast feeding unless your doctor considers it essential.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

You may feel drowsy or sleepy while 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 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) and for treatment and prevention of feeling sick or being sick (such as travel sickness):

Adults including elderly

1 Tablet (25mg) once a day at bedtime. This may be increased to a maximum of 1 tablet (25mg) taken three times a day.

Maximum daily dose is 75mg.

As a sedative (under the advice of a doctor only)

Children 6-12 years

1 Tablet (25mg) taken at bedtime.

Children under 6 years of age

Phenergan Tablets must not be given to children under 2 years of age because of the potential for serious breathing difficulties which may be fatal.

Phenergan Tablets are not recommended in children 2 to 5 years of age due to the potential for psychiatric and nervous system adverse effects (see section 4).

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, 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 heartbeat or forceful heartbeat (palpitations)
- Tiredness which lasts for a long time, this may be due to a blood problem called haemolytic anaemia or you develop a severe infection including tiredness, high fever with chills. This could be due to a blood problem called agranulocytosis.
- Over-active behaviour in children.

A very serious and sometimes deadly health problem called neuroleptic malignant syndrome (NMS) may happen. Stop treatment and call your doctor straight away if you have high fever, muscle cramps or stiffness, dizziness, very bad headache, fast heartbeat, confusion, agitation, , hallucinations, or are sweating a lot.

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

Unknown:

- 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).
- Eosinophilia which is an increase in the number of eosinophils (a type of white blood cells) found in a blood test.
- A feeling of aggression, hallucination and hyperactivity.

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

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

5. How to store Phenergan Tablets

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

Do not use 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.

Do not store above 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 protect the environment.

6. Contents of the pack and other information

What Phenergan Tablets contain

Each tablet contains 25mg of the active substance, promethazine hydrochloride. The other ingredients are lactose, monohydrate, maize starch, povidone K30, magnesium stearate, macrogol 200, Indigo Carmine (E132), Titanium Dioxide (E171) and hypromellose.

What Phenergan Tablets looks like and contents of the pack

Pale blue circular tablets with 'PN25' on one side and the other side is plain. Phenergan tablets are available in blister packs of 7, 10, 20, 28 or 56 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Opella Healthcare France SAS
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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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