Phenergan® 25mg Film-Coated Tablets

(promethazine hydrochloride)

Patient Information 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.

Your medicine is called Phenergan 25mg Film-Coated Tablets but will be referred to as Phenergan Tablets throughout this leaflet. Please note that this leaflet also contains information about other strengths of this medicine.

What is 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
Phenergan Tablets are used to treat the following conditions:
* 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: to treat adults with difficulty sleeping (insomnia)
* For short term use: as a sedative for children aged 6 years and above

2 What you need to know before you take Phenergan Tablets

Do not take Phenergan Tablets if:
* The person taking the medicine is under 6 years of age.
* You are allergic (hypersensitive) 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.
* 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 'Other medicines and Phenergan Tablets')
* 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.

Warnings and precautions
Check with your doctor or pharmacist before taking Phenergan Tablets 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 an 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.
* 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
Phenergan Tablets can make your skin more sensitive to sunlight. Keep out of direct sunlight while taking this medicine.

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.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Phenergan 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 Phenergan Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take 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.

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 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). Phenergan 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.

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

Pregnancy and breastfeeding
Use of Phenergan 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, 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 breastfeeding. This is because small amounts may pass into mothers' milk. This can be harmful to your baby.

If you are breastfeeding or planning to breastfeed, 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 Phenergan Tablets affect you.

Phenergan Tablets contains 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 Phenergan 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 Phenergan 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

Phenergan® 25mg Film-Coated Tablets

(promethazine hydrochloride)

Patient Information Leaflet (continued)

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:
* Phenergan Elixir 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 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 (25-50mg) taken at night

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 symptoms of an overdose may occur: fits (seizures), impaired consciousness, coma, uneven heart beat and depressed breathing. Children may experience excitation, unsteady or uncontrollable movements especially of the hands or feet, hallucinations, limited ability to learn and impairments in thinking, learning, or memory.

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.

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:
* 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
* 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 hyperactivity in children

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days.
* 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 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 Phenergan Tablets

* Keep out of the sight and reach 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.
* If your doctor tells you to stop taking this medicine, return any unused tablet to your pharmacist (chemist) for safe disposal. Only keep this medicine if your doctor tells you to.
* If your medicine becomes discoloured or shows any other signs of deterioration, consult your pharmacist who will tell you what to do.
* Do not store above 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 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, 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.

Manufacturer and Licence Holder
This medicine is manufactured by FAMAR HEALTH CARE SERVICES MADRID S.A.U., Avenida De Leganes, Alcorcon, Madrid, Spain and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

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.

P PL 15184/1847 Phenergan 25mg Film-Coated Tablets

Phenergan is a registered trademark of SANOFI.

Revision date: 23/09/24

Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Lexon (UK) Limited,
Tel: 01527 505414 to obtain the leaflet in a format suitable for you.

Promethazine Hydrochloride 25mg Film-Coated Tablets

Patient Information Leaflet

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* Ask your pharmacist if you need more information or advice
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* You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

Your medicine is called Promethazine Hydrochloride 25mg Film-Coated Tablets but will be referred to as Promethazine Tablets throughout this leaflet. Please note that this leaflet also contains information about other strengths of this medicine.

What is in this leaflet:

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2. What you need to know before you take Promethazine Tablets
3. How to take Promethazine Tablets
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1 What Promethazine Tablets are and what they are used for

Promethazine 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 Tablets are used for
Promethazine Tablets are used to treat the following conditions:
* To treat allergic conditions such as hay fever or rashes (like nettle rash or hives)
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* For short term use: to treat adults with difficulty sleeping (insomnia)
* For short term use: as a sedative for children aged 6 years and above

2 What you need to know before you take Promethazine Tablets

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* You are taking a medicine for depression called a monoamine oxidase inhibitor (MAOI). Also do not take Promethazine 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 Tablets')
* 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 Promethazine Tablets.

Warnings and precautions
Check with your doctor or pharmacist before taking Promethazine Tablets 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 an 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.
* 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 Tablets can make your skin more sensitive to sunlight. Keep out of direct sunlight while taking this medicine.

Tests
Taking Promethazine Tablets may affect the results of certain tests. These include some pregnancy tests and skin tests. Promethazine 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 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 Tablets

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

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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 Tablets contains 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 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 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

Promethazine Hydrochloride 25mg Film-Coated Tablets

Patient Information Leaflet (continued)

How much to take
The recommended dose is:
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* 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)
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* Promethazine Elixir should be given in this age group

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If you forget to take Promethazine Tablets
Do not take a double dose to make up for a forgotten dose
* If you are taking Promethazine Tablets for an allergic condition - take your medicine as soon as you remember, then carry on as before
* If you are taking Promethazine 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 Tablets can cause side effects, although not everybody gets them.

Stop taking Promethazine Tablets and see a doctor or go to a hospital straight away if you notice any of the following side effects:
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* Liver problems that may cause the eyes or skin to go yellow (jaundice) and darkening of urine
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* Tiredness which lasts for a long time. This may be due to a blood problem called anaemia.
* 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.
* 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).

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5 How to store Promethazine Tablets

* Keep out of the sight and reach of children.
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