



PACKAGE LEAFLET:  
INFORMATION FOR THE USER

# Phenergan<sup>®</sup>

## 2.5% w/v

### Solution for Injection

*promethazine hydrochloride*



**Is this leaflet hard to see or read?  
Phone 01 403 5600 for help**

**Read all of this leaflet carefully before you start having this medicine**

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

**In this leaflet:**

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

#### 1. WHAT PHENERGAN INJECTION IS AND WHAT IT IS USED FOR

Phenergan Injection contains 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 Injection is used for**

- To treat allergic conditions such as hay fever or rashes (like nettle rash or hives).
- As a sedative. This is a medicine given to reduce awareness or make you feel relaxed and at ease
- To help you feel more relaxed before an operation
- To treat adults with difficulty sleeping (insomnia)

#### 2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN PHENERGAN INJECTION

**Do not have 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 Injection (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 Injection 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
- You have had something called Reye’s Syndrome or possible Reye’s Syndrome - signs include being sick and confused following a viral illness.

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 having Phenergan Injection.

**Warnings and precautions**

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

**Take special care with Phenergan Injection**

**Check with your doctor or pharmacist before having 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 increased pressure in the eye (narrow angle glaucoma)

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

**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 Injection can affect the way some medicines work. Also some medicines can affect the way Phenergan Injection 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.

**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).
- Medicines for high blood pressure
- Medicines for fits (epilepsy)
- Medicines for diabetes. Your doctor may need to change the dose of your medicine
- Phenergan Injection may hide the side effects of these medicines

**Having Phenergan Injection with food and drink**

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

**Pregnancy and breast-feeding**

Phenergan Injection should not be given 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, dizzy or confused while having this medicine or in the morning 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 Injection**

This medicine contains:

- Sodium sulphite and sodium metabisulphite. These may rarely cause severe allergic (hypersensitivity) reactions and difficulty breathing, wheezing and tightness in the chest (bronchospasm)
- Sodium. It contains 0.4mg sodium per ml and is essentially ‘sodium- free’.

#### 3. HOW PHENERGAN INJECTION IS GIVEN

Your medicine will normally be given to you by a doctor or nurse. This is because it needs to be given by a deep injection into a muscle or by a slow injection into the vein.

**Having this medicine**

- This medicine is usually given by a deep injection into a muscle. It can also be given by a slow injection into the vein after dilution using water for injection

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- If you feel the effect of your medicine is too weak or too strong, tell your doctor

How much is given

The usual dose is:

Children 5-10 years:

- 6.25 to 12.5mg given by deep injection into a muscle

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

- 25 to 50mg given by deep injection into a muscle. It can also be given in an emergency by a slow injection into a vein after being mixed with water for injections. The maximum dose is 100mg. If you are not sure why you are being given Phenergan Injection or have any questions about how much Phenergan Injection is being given to you, speak to your doctor or nurse.

Exposure to sunlight

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

If you have more Phenergan Injection than you should

It is unlikely that your doctor or nurse will give you too much medicine. Your doctor and nurse will be monitoring your progress, and checking the medicine that you are given. Always ask if you are not sure why you are getting a dose of medicine. 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 miss a dose of Phenergan Injection

Your doctor or nurse will have instructions on when to give you this medicine. It is unlikely that you will not be given the medicine as it has been prescribed. However if you do think you have missed a dose, tell your doctor or nurse. If you have any further questions on the use of this product, ask your doctor or nurse.

Tests

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

4. POSSIBLE SIDE EFFECTS

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

Tell a doctor or nurse straight away if you have:

- 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

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 eyesight or you can not 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.

You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: [www.hpra.ie](http://www.hpra.ie)

E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

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

5. HOW TO STORE PHENERGAN INJECTION

This medicine will be kept by your doctor or pharmacist in a safe place where children cannot see or reach it. Phenergan Injection should not be used after the expiry date which is stated on the carton and ampoule after EXP. The expiry date refers to the last day of that month. Store in the original package in order to protect from light.

Once the ampoule is opened, the solution should be used immediately. Any unused solution should be discarded. Discoloured solutions should not be used.

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 Injection contains

- Each 1ml ampoule contains 25mg of the active substance, promethazine hydrochloride
- The other ingredients are sodium sulphite anhydrous (E221), sodium metabisulphite (E223) and water for injection.

What Phenergan Injection looks like and contents of the pack

Phenergan Injection is a colourless or almost colourless solution. Your solution for injection is available in cartons containing 10 x 1ml ampoules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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T/A SANOFI  
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Fax: 01 403 5687  
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Manufacturer

**SANOFI S.p.A.**  
Località Valcanello  
03012 Anagni  
Italy

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.

This leaflet was last revised in March 2015.

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