



**PACKAGE LEAFLET:  
INFORMATION FOR THE USER**

# Phenergan® 25mg/ml Solution for Injection

Promethazine hydrochloride

sanofi



**Is this leaflet hard to see or read?  
Phone 0800 035 2525 for help**

**Read all of this leaflet carefully before having this medicine because it contains important information for you**

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor nurse or pharmacist
- If you get any side-effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

**What is 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 will be given
4. Possible side effects
5. How to use 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 for both adults and children. This is a medicine given to reduce awareness or make you feel relaxed and at ease
- To treat adults with difficulty sleeping (insomnia)
- To help you feel more relaxed before an operation

**2. What you need to know before you are given Phenergan Injection**



**Do not use Phenergan Injection if:**

- X The person taking the medicine is under 2 years of age
  - X 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
  - X 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, nurse or pharmacist (see “Other medicines and Phenergan Injection”)
  - X The person is unconscious (in a coma) or suffers from severe dizziness, drowsiness or headache
- You should not be given this medicine if any of the above applies to you. If you are not sure, talk to your doctor, nurse or pharmacist before having Phenergan Injection.



**Warnings and precautions**

**Check with your doctor or nurse before having Phenergan Injection if:**

- ▲ You have difficulty breathing, wheezing, tightness in the chest (asthma) or an infection in your lungs (bronchitis).
- ▲ You have a seizure disorder 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 a headache due to dehydration or high blood pressure.
- ▲ 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 Injection can make your skin more sensitive to sunlight. Keep out of direct sunlight while taking this medicine.

**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.

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

**Children and adolescents**

Do not use in children less than 2 years of age.



**Other medicines and Phenergan Injection**

Tell your doctor, nurse 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 Injection can affect the way some medicines work. Also some medicines can affect the way Phenergan Injection works.

**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, nurse or pharmacist



**Also tell your doctor, nurse 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 Injection may hide the side effects of these medicines
- Medicines for high blood pressure
- Medicines for fits (epilepsy)
- Medicines for diabetes. Your doctor may need to change the dose of your medicine
- Medicines for the treatment of irregular heartbeats (antiarrhythmics such as quinidine and amiodarone)
- Antimicrobials (such as erythromycin and levofloxacin) for the treatment of infections.

**Phenergan Injection with alcohol**

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

**Pregnancy and breastfeeding**

Use of Phenergan Injection is not recommended during pregnancy. Talk to your doctor before having 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. You should not have Phenergan Injection 2 weeks before you give birth.

You should not have Phenergan Injection 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, nurse or pharmacist before taking any medicine.

Turn Over





### Driving and using machines

You may feel drowsy, dizzy, confused or have blurred vision while having this medicine or in 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 Injection affects you.

### Phenergan Injection 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 will be 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
- 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:

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

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

- 25-50mg 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.

### 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.

## 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:

- 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.
- Over-active behaviour in children

### Tell your doctor, nurse or pharmacist if any of the following side effects get serious or lasts longer than a few days.

- Dry mouth, blurred eyesight or you can not pass water (urine)
- Feeling drowsy or sleepy, tiredness, disorientation, having nightmares, headaches, feeling restless
- If you have a headache this may be as a result of high blood pressure and/or dehydration and you are advised to see your doctor.
- 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, nurse or pharmacist. 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 Phenergan Injection

This medicine will be kept by your doctor or nurse in a safe place where children cannot see or reach it

Do not have Phenergan Injection 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 carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. 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 or 10 x 2ml ampoules.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

#### Marketing Authorisation Holder

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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, nurse or pharmacist.

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