

Package leaflet: Information for the user

Phenergan 5mg/5ml Oral Solution promethazine hydrochloride

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 have 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.

In this leaflet:

1. What Phenergan Oral Solution is and what it is used for
2. What you need to know before you take Phenergan Oral Solution
3. How to take Phenergan Oral Solution
4. Possible side effects
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6. Contents of the pack and other information

1. What Phenergan Oral Solution is and what it is used for

Phenergan Oral Solution 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.

Phenergan 5mg/5ml oral solution also contains Sodium Metabisulphite (E223), this may rarely cause severe hypersensitivity reactions and bronchospasm.

What Phenergan Oral Solution is used for

- To treat allergic conditions such as hay fever or rashes (like nettle rash or hives).
- To prevent nausea or vomiting (e.g. travel sickness).

2. What you need to know before you take Phenergan Oral Solution

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 Oral Solution (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 Oral Solution 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 diabetes. This medicine contains hydrogenated glucose syrup which is not suitable for diabetics (see ‘Important information about some of the ingredients of Phenergan Oral Solution’ below).
- 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 Oral Solution.

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 Oral Solution

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 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 Oral Solution.

Children under 6 years of age

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

Phenergan Oral Solution is 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 Oral Solution can affect the way some medicines work. Also some medicines can affect the way Phenergan Oral Solution 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 the treatment of irregular heartbeats (antiarrhythmics)
- Antidepressants
- Antipsychotics
- Antimicrobials

Phenergan Oral Solution may hide the side effects of these medicines.

Taking Phenergan Oral Solution with food and drink

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

Pregnancy and breast-feeding

Phenergan Oral Solution 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 or in the morning after taking this medicine. If this happens, do not drive or use any tools or machines.

- **Phenergan Oral Solution contains maltitol liquid (Hydrogenated glucose syrup).** 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. Maltitol may have a mild laxative effect.
- **Phenergan Oral Solution contains sodium sulphite and sodium metabisulphite.** These may rarely cause severe allergic (hypersensitivity) reactions and difficulty breathing, wheezing and tightness in the chest (bronchospasm).
- **Phenergan Oral Solution contains sodium.** This medicine contains 37 mg sodium (main component of cooking/table salt) in each 5 ml. This is equivalent to 1.9% of the recommended maximum daily dietary intake of sodium for an adult.
- **Phenergan Oral Solution contains alcohol.** This medicine contains 0.03 mg of alcohol (ethanol) in each 5 ml which is equivalent to 0.006 mg/ml. The amount in 5 ml of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take Phenergan Oral Solution

The amount you need to take depends on the reason you are taking Phenergan Oral Solution. 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
- After use, wipe the neck of the bottle with a clean damp cloth. This will remove any liquid that is left, before putting the cap back on
- 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):

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Children 6-10 years

A single dose of two to five 5ml spoonfuls (10-25mg) taken at bedtime Or one or two 5ml spoonfuls (5-10mg) twice a day.
Maximum daily dose is 5 x 5ml spoonfuls (25mg)

Adults including elderly

Five 5ml spoonfuls (25mg) once a day at bedtime.

This may be increased to a maximum of five 5ml spoonfuls (25mg) taken three times a day.

Maximum daily dose is 15 x 5ml spoonfuls (75mg)

The use of Phenergan tablets to provide these doses is recommended

For treatment and prevention of feeling sick or being sick (such as travel sickness)

Children 6-10 years

Two 5ml spoonfuls (10mg) taken the night before the journey. Repeat after 6-8 hours as required.

Adults including elderly

Five 5ml spoonfuls (25mg) taken the night before the journey Repeat after 6-8 hours as required.

The use of Phenergan tablets to provide this dose is recommended.

Children under 6 years of age

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

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

If you take more Phenergan Oral Solution than you should

If you take more Phenergan Oral Solution 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 have taken. Also do this if a child under 2 years of age swallows some of this 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 problems.

In adults: Feeling sleepy or drowsy, fits, very fast, uneven or forceful heartbeat (palpitations), loss of consciousness, breathing problems.

If you forget to take Phenergan Oral Solution

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

- If you are taking Phenergan Oral Solution for an allergic condition - take your medicine as soon as you remember, then carry on as before.
- If you are taking Phenergan Oral Solution 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 Oral Solution may affect the results of certain tests. These include some pregnancy tests and skin tests. Phenergan Oral Solution should not be taken at least 3 days before the start of a skin test.

4. Possible side effects

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

Stop taking Phenergan Oral Solution 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)
- Irregular heartbeat
- 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 Oral Solution

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

Do not use Phenergan Oral Solution after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original container in order to protect from light. Use within one month of opening the bottle.

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 Oral Solution contains

- Each 5ml of solution contains 5mg of the active substance, promethazine hydrochloride.
- The other ingredients are maltitol liquid, citric acid (E330), sodium citrate, ascorbic acid, sodium sulphite anhydrous (E221), sodium benzoate (E211), sodium metabisulphite (E223), orange juice flavour (contains ethanol), caramel HT, acesulfame potassium (E950) and purified water.

What Phenergan Oral Solution looks like and contents of the pack

A clear, golden, syrupy liquid contained in an amber glass bottle. Your Oral Solution is available in glass bottles of 100ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Opella Healthcare France SAS
157 avenue Charles de Gaulle

92200 Neuilly-sur-Seine
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Manufacturer

Unither Liquid Manufacturing
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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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