

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Phenergan Elixir

5mg/5ml Oral Solution

promethazine hydrochloride

SANOFI 

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

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.

What is in this leaflet :

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

1. What Phenergan Elixir is and what it is used for



Phenergan Elixir 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 Elixir is used for

Phenergan Elixir is used to treat the following

conditions:

- For short term use: to treat adults with difficulty sleeping (insomnia)
- To treat allergic conditions such as hay fever or rashes (like nettle rash or hives)
- To stop you feeling sick (nausea) or being sick (vomiting) such as travel sickness
- For short term use: as a sedative for children aged 2 years and above

2. What you need to know before you take Phenergan Elixir



Do not take this medicine 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 Phenergan Elixir (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
 - X You are taking a medicine for depression called a monoamine oxidase inhibitor (MAOI). Also do not take Phenergan Elixir 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)
 - X 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 Elixir.



Warnings and precautions

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 diabetes. This medicine contains hydrogenated glucose syrup (see 'Important

information about some of the ingredients of Phenergan Elixir' below)

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



Other medicines and Phenergan Elixir

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 Elixir can affect the way some medicines work. Also some medicines can affect the way Phenergan Elixir 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). Phenergan Elixir may hide the side effects of these medicines

Phenergan Elixir with food and drink

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

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant. Phenergan Elixir should not be taken in the 2 weeks before birth.

You should not take Phenergan Elixir if you are breast-feeding. This is because small amounts may pass into mothers' milk. This can be harmful to your baby.

If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist 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 Elixir contains:

• Hydrogenated glucose syrup (maltitol liquid).

This is a type of carbohydrate which the body will convert into small amounts of sugar. The maximum 25ml single dose of Phenergan Elixir is equivalent to approximately 5 grams of sugar, or one teaspoon of sugar/ sugar lump. Taking this amount of Phenergan Elixir is unlikely to affect the control of your diabetes or require you to increase your diabetes medication. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine. Hydrogenated glucose syrup may have a mild laxative effect. The calorific value of hydrogenated glucose syrup is 2.3kcal/g. A 5ml dose (one teaspoon) contains approximately 10kcal.

• 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 37mg sodium per dose (5ml). Take this into account if you are on a controlled sodium diet

• Sodium benzoate:

This medicine contains 5mg sodium benzoate in each 5ml dose, which is equivalent to 1mg/ml. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take Phenergan Elixir

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 Elixir. 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
- 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, talk to your doctor

How much to take

The recommended dose is:

For allergies (such as hay fever, rashes and hives)

Children 2-5 years:

- Either a single dose of one to three 5ml spoonfuls OR one 5ml spoonful twice a day

- DO NOT give more than three 5ml spoonfuls a day

Children 5-10 years:

- Either a single dose of one to five 5ml spoonfuls OR one or two 5ml spoonfuls twice a day

- DO NOT give more than five 5ml spoonfuls a day

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

- Start with two 5ml spoonfuls twice a day
- This may be increased to a maximum of four 5ml spoonfuls three times a day

For children over 10 years and adults, Phenergan Tablets may be more convenient

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

Children 2-5 years:

- One 5ml spoonful the night before the journey
- This may be repeated after 6-8 hours if necessary

Children 5-10 years:

- Two 5ml spoonfuls the night before the journey
- This may be repeated after 6-8 hours if necessary

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

- Five 5ml spoonfuls the night before the journey
- This may be repeated after 6-8 hours if necessary

For children over 10 years and adults, Phenergan Tablets may be more convenient

As a short term paediatric sedative and for short term treatment of insomnia in adults

Children 2-5 years:

- Three or four 5ml spoonfuls as a single dose at night time

Children 5-10 years:

- Four or five 5ml spoonfuls as a single dose at night time

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

- Use of Phenergan Tablets is recommended

Use this medicine only as recommended. Do not exceed the recommended dose.

Exposure to sunlight

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

If you take more Phenergan Elixir than you should

If you take more Phenergan Elixir 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 Elixir

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

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

4. Possible effects

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

Stop taking Phenergan Elixir 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 the 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 anaemia
- Over-active behaviour in children

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
- 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 Elixir

- Keep this medicine out of the sight and reach of children
- Do not use Phenergan Elixir after the expiry date which is stated on the carton and bottle label. The expiry date refers to the last day of that month
- Do not use Phenergan Elixir after the bottle has been opened for more than a month
- Store below 25°C
- Keep the bottle in the outer carton 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 Elixir contains.

- Each 5ml of solution contains 5mg of the active substance, promethazine hydrochloride.
- The other ingredients are hydrogenated glucose syrup (maltitol liquid), orange juice flavour, caramel (E150), sodium benzoate (E211), sodium sulphite anhydrous (E221), sodium metabisulphite (E223), ascorbic acid (E300), citric acid anhydrous (E330), sodium citrate (E331), acesulphame potassium (E950) and water.

What Phenergan Elixir looks and smells like and contents of the pack

A clear, golden, syrupy liquid with an odour of oranges contained in an amber glass bottle with a child resistant cap and tamper-evident ring. Your elixir is available in glass bottles of 100ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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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.

This leaflet was last revised in 03/2021

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