

**PACKAGE LEAFLET:  
INFORMATION FOR THE USER**

# Phenergan Night Time

## 25mg Film-coated Tablets

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

### 1. What Phenergan Night Time is and what it is used for



Phenergan Night Time 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 Night Time is used for

- For short term use: to treat adults with difficulty sleeping (insomnia)
- For short term use: as a sedative for children aged 16 years and above

### 2. What you need to know before you take Phenergan Night Time



#### Do not take Phenergan Night Time if:

- ✗ The person taking the medicine is under 16 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 Night Time 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 Night Time")
- ✗ 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 Night Time.



#### Warnings and precautions

Check with your doctor or pharmacist before taking Phenergan Night Time 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 any personal or family history of heart disease
- ▲ You have irregular heartbeat

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- ▲ 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

This medicine is for short term sleeping problems. It should not be used for more than 7 days without talking to your doctor.

### Exposure to sunlight

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

### Tests

Taking Phenergan Night Time may affect the results of certain tests. These include some pregnancy tests and skin tests. Phenergan Night Time 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 Night Time.



### Other medicines and Phenergan Night Time

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 Night Time can affect the way some medicines work. Also some medicines can affect the way Phenergan Night Time works.

### In particular, do not take this medicine, and tell your doctor or pharmacist, 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 Night Time may hide the side effects of these medicines
- 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 Night Time with alcohol

Do not drink alcohol while you are taking Phenergan Night Time. 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 Night Time should not be taken 2 weeks before birth.

You should not take Phenergan Night Time 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 after taking this medicine or the morning after taking this medicine. If this happens, do not drive or use any tools or machines.

### **Phenergan Night Time 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 Night Time**

Always take this medicine exactly as described in the leaflet or as your doctor or pharmacist has told you. 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
- 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

#### **How much to take**

The recommended dose is:

##### **Adults (including the elderly) and children over 16 years of age:**

- One or two tablets (25-50mg) taken at night

#### **If you take more Phenergan Night Time than you should**

If you or your child takes more Phenergan Night Time 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.

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 heartbeat and breathing difficulties.

**In adults:** Feeling sleepy or drowsy, fits, loss of consciousness, uneven heart beat and breathing difficulties

### **If you forget to take Phenergan Night Time**

**Do not** take a double dose to make up for a forgotten dose, 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 Night Time can cause side effects, although not everybody gets them.

#### **Stop taking Phenergan Night Time 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
- 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)
- Tiredness which lasts for a long time. This may be due to a blood problem called anaemia.

#### **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)

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- 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](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 Night Time

Keep this medicine out of the sight and reach of children

Do not take Phenergan Night Time 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

Store below 30°C

Store in the original 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 Night Time contains.

- 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 Night Time looks 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 14.

#### Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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#### Manufacturer

FAMAR HEALTH CARE SERVICES MADRID, S.A.U.

Avda. Leganes, 62,

Alcorcon 28923 (Madrid) Spain

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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#### SIX HELPFUL STEPS FOR A GOOD NIGHT'S SLEEP

- Go to bed when you feel tired and avoid sleep during the day.
- Get up at the same time every morning.
- Make time for some gentle exercise during the day, preferably in the afternoon or early evening but not just before going to bed.
- Sleep in a dark, well ventilated room on a comfortable bed.
- Every night, before bedtime, do something to help you relax and take your mind off the stresses of the day.
- A small warm milky drink may help you sleep, but avoid alcohol, tea, coffee and cocoa since these may keep you awake, as can late night eating.

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**FAMAR**

*Artworks Department. Madrid. Spain*

**COLOURS**

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