Fonts : Times New Roman
Fonts Size :
Generic Name font size : 12 pt.
Composition fonts size : 9 pt.

Numark Night Time Sleep Aid 25 mg and 50 mg Tablets
Diphenhydramine Hydrochloride

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Leaflet Size : 170 x 280 mm
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170 mm

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PHARMA CODE

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Pharmacode Reading Direction

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Numark Night Time Sleep Aid 25 mg and 50 mg Tablets

Diphenhydramine 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 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.

What is in this leaflet

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

1. What Numark Night Time Sleep Aid Tablet is and what it is used for

Numark Night Time Sleep Aid Tablets contain the active substance diphenhydramine hydrochloride which is an antihistamine with sedative properties which induces drowsiness or sedation. It works by reducing the time needed to fall asleep and increases the depth and quality of sleep.

Numark Night Time Sleep Aid Tablets is used to aid relief of temporary sleep disturbance (difficulties sleeping) in adults and children over 16 years of age.

2. What you need to know before you take Numark Night Time Sleep Aid Tablets

Do not take Numark Night Time Sleep Aid Tablets:

- if you are allergic to diphenhydramine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you have a peptic ulcer
- if you have a blockage between your stomach and small intestine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Numark Night Time Sleep Aid Tablets

- if you suffer from myasthenia gravis (abnormal muscle function)
- if you suffer from seizures or have epilepsy
- if you have asthma, bronchitis or Chronic Obstructive Pulmonary Disease (COPD)
- if you have narrow angle glaucoma
- if you have an enlarged prostate
- if you have difficulty urinating
- if you have moderate to severe liver or kidney problems
- if you are elderly, particularly if you also suffer from confusion.

This medicine is for short term sleeping problems. It may not work as well if you use it continuously. If your problems with sleeping persist, see your doctor for advice. Do not continue to take it for longer than 2 weeks without consulting a doctor.

Other medicines and Numark Night Time Sleep Aid Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor or pharmacist if you are taking any of the following:

- other antihistamines including those used on your skin and in cough and cold medicines
- tranquillisers or anxiolytics (sedatives) used to treat anxiety e.g. diazepam
- hypnotics (e.g. nitrazepam) used to help you sleep better
- monoamine oxidase inhibitors (MAOIs) for depression (e.g. phenelzine) or if you have stopped taking an MAOI within the last two weeks
- metoprolol (a beta blocker) used to treat high blood pressure, angina, irregular heart beat or overactive thyroid
- venlafaxine used to treat depression
- antimuscarinics which relax smooth muscles and are used for example in Parkinsons Disease, irritable bowel syndrome and incontinence e.g. procyclidine, trihexyphenidyl, atropine, oxybutinin, fesoterodine
- tricyclic antidepressants (e.g. imipramine, amitriptyline).

Numark Night Time Sleep Aid Tablets with alcohol

Do not drink alcohol if you are taking this medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines:

This medicine causes drowsiness and sedation and may also cause dizziness, blurred vision, disturbance in attention and slower reaction times. Do not drive or operate machinery while you are affected in this way.

Numark Night Time Sleep Aid Tablets contain lactose

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Numark Night Time Sleep Aid Tablets

Always take 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 recommended dose is:
Adults and children over 16 years:

25mg strength tablets: Take two tablets 20 minutes before going to bed.
50mg strength tablets: Take one tablet 20 minutes before going to bed.
Do not exceed the stated dose. Do not continue to take it for longer than 2 weeks without consulting a doctor.

Use in children:
Do not use in children under 16 years of age.

This medicine is for oral use. Swallow the tablets whole with water.

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If you take more Numark Night Time Sleep Aid Tablets than you should

If you take too much of this medicine it is likely to result in effects similar to those listed below in section 4 Possible Side Effects. Other effects may include dilated pupils, fever, flushing, agitation, shaking, movement disorder, seeing or hearing things that are not real or ECG changes. A large overdose may cause abnormal muscle breakdown which can lead to kidney problems, fits, delirium, loss of contact with reality, irregular heartbeat, coma or cardiovascular collapse. Talk to your doctor or pharmacist if you take too many tablets. Take the medicine pack with you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following occur STOP TAKING the tablets IMMEDIATELY and contact your doctor, as these may be signs of an allergic reaction:

- difficulty breathing or shortness of breath, swelling of the face, mouth or throat
- rash, hives (itchy, raised red weals).

If you notice any of the following effects tell your doctor straightaway:
- fever, chills, sore throat, infections. These may be signs of a blood disorder
- faster heartbeat, irregular heartbeat
- fits, difficulty making or controlling movements.

Tell your doctor, pharmacist or nurse if you suffer from any of the following other effects:

Common effects (may affect up to 1 in 10 people):
- sedation, drowsiness, dizziness, unsteadiness, disturbance in attention
- dry mouth
- fatigue

Other effects:
- palpitations (feeling your heartbeat)
- headache, tingling or numbness (pins and needles)
- depression, sleep disturbances
- confusion, excitation e.g. increased energy, restlessness, nervousness (the elderly are more likely to experience these effects)
- difficulty urinating or inability to pass urine
- thicker bronchial mucus
- blurred vision
- feeling or being sick, stomach problems
- muscle twitching

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 Numark Night Time Sleep Aid Tablets

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

Do not use this medicine after the expiry date which is stated on the label, carton or blister after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Numark Night Time Sleep Aid Tablets contains

The active substance is diphenhydramine hydrochloride. Each tablet contains either 25 mg or 50 mg diphenhydramine hydrochloride. The other ingredients are Lactose monohydrate, Maize Starch and Magnesium Stearate.

What Numark Night Time Sleep Aid tablets looks like and contents of the pack

Numark Night Time Sleep Aid 25 mg Tablets are white, circular, normal convex tablets marked with '25' on one side & plain on the reverse.

Numark Night Time Sleep Aid 50 mg Tablets are white, circular, biconvex tablets with embossed '50' on one side & plain on other side.

Numark Night Time Sleep Aid Tablets are available in cartons containing blister packs of Aluminium-PVC/PVDC 20's along with a leaflet inside.

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This leaflet was last revised in 08/2025.

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PL 43461/0065 MPLLDIPXXXXTB020
PL 43461/0066 FPLNUM431V01