Package leaflet: Information for the user

Diphenhydramine Hydrochloride

Read all of this leaflet 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.

In this leaflet:

- 1. What Numark Sleep Aid 25mg Tablets are and what they are used for
- 2. What you need to know before you take Numark Sleep Aid 25mg Tablets
- 3. How to take Numark Sleep Aid 25mg Tablets
- 4. Possible side effects
- 5. How to store Numark Sleep Aid 25mg Tablets
- 6. Contents of the pack and other information

1. What Numark Sleep Aid 25mg Tablets are and what they are used for

Numark Sleep Aid 25mg Tablets are used to relieve temporary sleeping difficulties. The active ingredient is diphenhydramine hydrochloride, an antihistamine that causes sleepiness or drowsiness. Temporary difficulties in getting a good night's sleep can be caused by various problems such as stress, jet lag or personal problems such as bereavement. In sleep problems of this type, this medicine has been shown to help sufferers to fall asleep faster, have a longer and deeper sleep, and to wake up feeling rested in the morning.

Do not take this medicine for more than 2 weeks without consulting your doctor.

2. What you need to know before you take Numark Sleep Aid 25mg Tablets



Do not take this medicine:

- if you have ever had an allergic reaction to diphenhydramine hydrochloride or any of the other ingredients (listed in Section 6)
- if you have an obstruction in your stomach or gut (for example, because of an ulcer).



Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

- if you have asthma, bronchitis or Chronic Obstructive Pulmonary Disease (COPD)
- if you have narrow-angle glaucoma (a form of raised pressure in the eye)
- · if you have an enlarged prostate or urinary retention
- if you have moderate to severe liver or kidney disease
- if you have myasthenia gravis, epilepsy or seizure disorders
- If your sleeping difficulties persist, talk to your doctor or pharmacist
- This medicine may get less effective if you use it continuously.



Other medicines and Numark Sleep Aid 25mg

Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed medicines; particularly tricyclic antidepressants, monoamine oxidase inhibitors (MAOIs prescribed for depression) within the last two weeks, atropine (used to dilate pupils of the eyes) or medicines which make you drowsy. Avoid the use of other antihistamines including those used on your skin and in cold and cough medicines, while taking this medicine.

Numark Sleep Aid 25mg Tablets with food, drink and alcohol Do not drink alcohol while using this

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Pregnancy, breast feeding and fertility

Talk to your doctor before taking this medicine if you are pregnant, trying to become pregnant, or breast feeding



Driving and using machines Do not drive or operate machinery. This medicine is intended to produce sleepiness or drowsiness

soon after the dose is taken.

Numark Sleep Aid 25mg Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, ask your doctor before taking this

3. How to take Numark Sleep Aid 25mg 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 for adults and children aged 16 years and over: Swallow 2 tablets with water 20 minutes before you go to bed.

Not to be used by children under 16 years. Not to be used by the elderly with confusion.



- Do not take more than the recommended dose.
- Do not take extra tablets if you wake up in the night.
- Do not take for more than 2 weeks without consulting a doctor.

If you take more Numark Sleep Aid 25mg Tablets than you should Contact your doctor or casualty department.

If you forget to take Numark Sleep Aid 25mg Tablets

Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time as described in this leaflet. 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 have side effects, although not everybody gets them

Common (may affect up to 1 in 10 people)

• The most common side effects are: tiredness, drowsiness, reduced attention, unsteadiness, dizziness or a dry mouth.

Not known (frequency cannot be estimated from the available data)

- Allergic reactions (such as rash, shortness of breath and swelling). blurred vision, palpitations (feeling your heart beat) or irregular heartbeat.
- Muscle twitching, convulsions, headache or pins and needles.
- Also nausea (feeling sick), vomiting (being sick), thicker bronchial mucus and difficulty passing urine.

Reporting of side effects:

If you get any side effects, talk to vour 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 By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Numark Sleep Aid 25mg Tablets

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

Do not use this medicine after the expiry date (EXP) stated on the pack. 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. Store in a dry place.

6. Contents of the pack and other information

What Numark Sleep Aid 25mg Tablets contain

- The active substance: Each tablet contains Diphenhydramine Hydrochloride 25 ma.
- The other ingredients are: Anhydrous lactose, microcrystalline cellulose, maize starch, stearic acid and silicon dioxide.

What Numark Sleep Aid 25mg Tablets look like and contents of the pack Packs of Numark Sleep Aid 25mg Tablets contain 4, 8, 16, 20 or 24 tablets. Not all pack sizes may be marketed.

Marketing authorisation holder is Omega Pharma Ltd., 32 Vauxhall Bridge Road. London, SW1V 2SA, United Kingdom and all enquiries should be sent to this address.

Manufacturer Wrafton Laboratories Ltd, Wrafton,

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