Nytol Original 25mg Tablets

Diphenhydramine Hydrochloride

Please read right through this leaflet before you start using this medicine. This medicine is available without prescription, but you still need to use Nytol Original carefully to get the best results from it.

- Keep this leaflet, you may need to read it again.
- If you have any questions, or if there is anything you do not understand, ask your pharmacist.

In this leaflet:

- 1.What Nytol Original does
- 2. Check before you take Nytol Original
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1. What Nytol Original does

Nytol Original is 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, Nytol 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.

2. Check before you take Nytol Original

Do not take Nytol:

- 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).

Take special care with Nytol Original

Talk to your doctor:

- 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.
- Do not drive or operate machinery.

Nytol Original is intended to produce sleepiness or drowsiness soon after the dose is taken.

- Do not drink alcohol while using Nytol.
- If you have been told by your doctor that you have an **intolerance to some sugars**, ask your doctor before taking this medicine.
- If your **sleeping difficulties** persist, talk to your doctor or pharmacist.
- Nytol may get less effective if you use it continuously.

If you are taking other medicines

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.

Pregnancy and breast feeding

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

3. How to take Nytol

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.

If you take too many tablets

Contact your doctor or casualty department.

4. Possible side effects

Like all medicines, Nytol can have side effects, but not everybody gets them:

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

Other side effects may include: allergic reactions (such as rash, shortness of breath and swelling), blurred vision, palpitations (feeling your heart beat) or irregular heart beat. Muscle twitching, convulsions, headache or pins and needles. Also nausea (feeling sick), vomiting (being sick), thicker bronchial mucus and difficulty passing urine.

If you do get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

5. How to store Nytol Original

Keep out of the reach and sight of children.

Do not use this medicine after the 'EXP' date shown on the pack.

Store in a dry place.

6. Further information

Active ingredient: Each tablet contains Diphenhydramine Hydrochloride 25 mg.

Other ingredients: Anhydrous lactose, microcrystalline cellulose, maize starch, stearic acid and silicon dioxide.

Packs of Nytol contain 4 or 16 tablets. Not all pack sizes may be marketed.

The 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.

The manufacturer is Wrafton Laboratories Ltd, Wrafton, Braunton, North Devon, EX33 2DL, U.K.

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