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Package leaflet: Information for the user

Nytol
Original 25_{mg} Tablets
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 Nytol is and what it is used for
2. What you need to know before you take Nytol
3. How to take Nytol
4. Possible side effects
5. How to store Nytol
6. Contents of the pack and other information

1. What Nytol is and what it is used for
Nytol 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.
Do not take Nytol for more than 2 weeks without consulting your doctor.

2. What you need to know before you take Nytol

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).

Warnings and precautions

Talk to your doctor or pharmacist before taking Nytol:

- 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.
- Nytol may get less effective if you use it continuously.

Other medicines and Nytol

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.

Nytol with food, drink and alcohol
Do not drink alcohol while using Nytol.

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

! Driving and using machines
Do not drive or operate machinery. Nytol is intended to produce sleepiness or drowsiness soon after the dose is taken.

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

3. How to take Nytol
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 Nytol than you should
Contact your doctor or casualty department.

! if you forgot to take Nytol
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, Nytol 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 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
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nytol
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 Nytol contains

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

What Nytol looks like and contents of the pack
Packs of Nytol 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, Braunton, North Devon, EX33 2DL, U.K.

This leaflet was last revised in May 2017.

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File title: 9913_LF03490C_G3U60FCJB1_Nytol Original 25mg 20s PIL_UK_v10
Item No.: G3U60FCJB1
OPI NO.: LF03490C
Last edit: 16th May 2017
Brand: Nytol
Variant: Original 25mg
Component: Leaflet 20s
Market/s: UK
Dimensions: 140 x 150mm (F166v2)
Printer: Nampack Liverpool
Substrate: Paper
EAN Code: N/A
PharmaCode: 539
Replacement number: 2538202
Manufacturing Site: Perrigo Wrafton
No. of colours: 1 (one)

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Process Black

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Regulatory Approval:

Sign:..... Date:.....

Name (please print):.....

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Marketing Approval:

Sign:.....

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Contact email:.....