140mm
12mm
125mm
3mm
5mm
140mm
150mm
1mm
10mm
TBA
PharmaCode TBA -->
40mm lead-in

Package leaflet: Information for the user

Nytol

One-a-Night 50mg 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 One-A-Night is and what it is used for
2.What you need to know before you take Nytol One-A-Night
3.How to take Nytol One-A-Night
4.Possible side effects
5.How to store Nytol One-A-Night
6.Contents of the pack and other information

1. What Nytol One-A-Night is and what it is used for

Nytol One-A-Night 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 One-A-Night 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 One-A-Night for more than 2 weeks without consulting your doctor.

2. What you need to know before you take Nytol One-A-Night

Do not take Nytol One-A-Night:
- **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 One-A-Night:

- 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 One-A-Night may get less effective if you use it continuously.

Other medicines and Nytol One-A-Night

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 One-A-Night with food, drink and alcohol
Do not drink alcohol while using Nytol One-A-Night.

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

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

Nytol One-A-Night 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 One-A-Night

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 1 tablet 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 One-A-Night than you should
Contact your doctor or casualty department.

If you forget to take Nytol One-A-Night
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 cause side effects, although not everybody gets them.
If any of the following occur STOP TAKING THIS MEDICINE 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, hive (itchy, raised red weals).

If you notice any of the following effects tell your doctor straightaway:
- Faster heartbeat, irregular heartbeat
- Fits, difficulty making or controlling movements.

Tell your doctor, pharmacist or nurse if you suffer from any of the following side effects:
Common side effects (may affect up to 1 in 10 people):
- Sedation, drowsiness, dizziness, unsteadiness, inattention
- Dry mouth
- Fatigue

Other side effects (frequency not known – cannot be estimated from the data available):
- Palpitations (feeling your heartbeat)
- Headache, tingling or numbness (pins and needles)
- 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
- Reduced sense of touch
- An irresistible urge to move your legs and other limbs (restless leg syndrome).

Reporting of side effects:
If you get any side effects, talk to your doctor or 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 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 Nytol One-A-Night

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 One-A-Night contains
- The active substance: Each tablet contains Diphenhydramine Hydrochloride 50 mg.
- The other ingredients are: Anhydrous lactose, microcrystalline cellulose, maize starch, stearic acid and silicon dioxide.

What Nytol One-A-Night looks like and contents of the pack
Packs of Nytol One-A-Night contain 4, 8, 10, 16 or 20 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.
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H3L60FCJB2

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Item No.: H3L60FCJB2
OPI No.: LF03489D
Last edit: 11th February 2021
Brand: Nytol
Variant: One-A-Night 50mg
Component: Leaflet 20s
Market/s: UK
Dimensions: 140 x 150mm (F166v2)

Substrate: Paper
EAN Code: N/A
PharmaCode: 578
Replacement number: H3L60FCJB1
Manufacturing Site: Perrigo Wrafton
No. of colours: 1 (one)

Process Black

Font 7pt/7pt Leading
87% horizonal scale

Regulatory Approval:

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

Name (please print):.....

Contact email:.....

Marketing Approval:

Sign:.....

Name (please print):.....

Contact email:.....