



Package leaflet: Information for the user



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 after 7 days.

What is in this leaflet

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2. What you need to know before you take Nytol One-A-Night 50mg Tablets
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4. Possible side effects
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6. Contents of the pack and other information

1. What Nytol One-A-Night 50mg Tablets are and what are they used for

These 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, Nytol One-A-Night 50mg Tablets have been shown to help people to fall asleep faster and have a longer and deeper sleep. You must talk to a doctor after 7 days if you do not feel better, or if you feel worse. You should not drive or operate machinery for at least 8 hours after taking the tablet.

2. What you need to know before you take Nytol One-A-Night 50mg Tablets

 Do not take these tablets:

- if you have ever had an allergic reaction to diphenhydramine hydrochloride or to 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).
- if you have a Phaeochromocytoma
- if you know you have a problem with 'QT interval prolongation'
- if you have or had a cardiovascular disease or if your heart rate is very low

- if you have low salt levels in your body (e.g. low level of potassium or of magnesium)
- if you are taking certain medicines for heart rhythm problems or medicines that may affect the heart rhythm
- if anyone in your close family has died suddenly of heart problems

 Warnings and precautions

Seek medical advice if sleeplessness persists, as insomnia may be a sign of serious underlying medical illness. Cases of dependence and / or abuse have been reported in young people. Signs of this occurring should be reported to a doctor.

Talk to your doctor or pharmacist before taking these tablets:

- 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 muscle weakness, epilepsy or seizure disorders.
- Skin allergy testing: do not take these tablets in the 3 days before skin tests for allergy. They may interfere with the results.

If your sleeping difficulties persist, talk to your doctor or pharmacist. Do not take these tablets for more than 7 days without consulting a doctor. Nytol One-A-Night 50mg Tablets may get less effective if you take them continuously.

 Children and adolescents

Do not use in children or adolescents under the age of 18 years.

 Other medicines and Nytol One-A-Night 50mg Tablets

- Do not take these tablets together with medicines that can produce a change in heart rhythm. If you are not sure, please consult your doctor before taking any.
- Do not use other antihistamines together with these tablets, including those used on the skin, or in cough and cold medicines.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. It's especially important to mention:

- certain antidepressants: tricyclics, or monoamine oxidase inhibitors (MAOIs) that you have taken within the last two weeks
- atropine (used to dilate pupils of the eyes)
- other medicines that make you drowsy.

 Taking Nytol One-A-Night 50mg Tablets with food, drink and alcohol

Do not drink alcohol while using these tablets.

 Pregnancy, breast feeding and fertility

Do not take Nytol One-A-Night 50mg Tablets if you are pregnant or breastfeeding. If you think you may be

pregnant or are planning to have a baby, ask your doctor for advice before taking these tablets.

 Driving and using machines


Do not drive or operate machinery. These tablets are intended to produce sleepiness or drowsiness soon after the dose is taken.

 Nytol One-A-Night 50mg 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 medicine.

3. How to take Nytol One-A-Night 50mg 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 aged 18 years and over: Swallow 1 tablet with water 20 minutes before you go to bed.

Not to be used by children under 18 years. Elderly patients or patients with liver or kidney problems should consult their doctor before taking this medicine.

-  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 7 days without consulting a doctor.

If you take more Nytol One-A-Night 50mg Tablets than you should: Contact your doctor or casualty department. If you forgot to take Nytol One-A-Night 50mg 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, Nytol One-A-Night 50mg Tablets can have side effects, but 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, palpitation (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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL

– Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nytol One-A-Night 50mg Tablets

Keep this medicine out of the sight and reach of children. Do not use this medicine after the EXP date shown on the pack. The expiry date refers to the last day of that month. Store below 25°C. Store in the original package in order to protect from light and moisture. 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 Nytol One-A-Night 50mg Tablets contains:

Active ingredients: Each tablet contains Diphenhydramine Hydrochloride 50 mg. Other ingredients: Anhydrous lactose, microcrystalline cellulose, maize starch, stearic acid and colloidal anhydrous silica.

What Nytol One-A-Night 50mg Tablets look like and contents of the pack
Nytol One-A-Night 50mg Tablets are white to off white, 15mm in length, oblong capsule shaped tablets embossed with "N50" logo on both sides packed into UPVC/PVdC blister packs with a heat sealable aluminium foil.

They are available in packs of 4, 8, 10, 16 and 20 tablets. Not all packs will be marketed.

Marketing Authorisation Holder:

Chefaro Ireland DAC, Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland.




Manufacturer:

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

This leaflet was last revised in 01/2017.

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	Item No.:	XXXXXX
	OPI No.:	LFXXXXXX
90	Replacement No.:	---
	Last edit:	23rd January 2017
	Brand:	Nytol
80	Variant:	One-A-Night 50mg
	Component:	Leaflet 20s
	Market/s:	Ireland
70	Dimensions:	182 x 249mm
	Reel Unwind:	---
	Spec. Ref.:	---
60	Substrate:	White Paper
	PharmaCode:	XXXXXX
	EAN Code:	N/A
50	Other Code/Spec.:	---
	Manufacturing Site:	Perrigo Wrafton
	Printer:	---
40	No. of Colours:	1
	 Process Black	 Cutter
30		
20		
10		
0		
		81 Rivington Street Shoreditch London EC2A 3AY United Kingdom awk contact: Phil Hinckley phil@oneagency.co +44 (0)7710 521027 +44 (0)203 008 6040

Marketing Approval:

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

Name (please print):.....

Contact email:.....

Regulatory Approval:

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

Name (please print):.....

Contact email:.....

Minimum font size
for body copy: 7/9.6pt