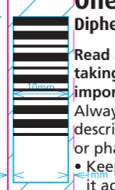
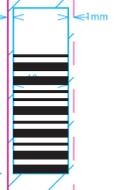


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Package leaflet: information for the user



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**
- What Nytol One-A-Night 50mg Tablets are and what are they used for
 - What you need to know before you take Nytol One-A-Night 50mg Tablets
 - How to take Nytol One-A-Night 50mg Tablets
 - Possible side effects
 - How to store Nytol One-A-Night 50mg Tablets
 - 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

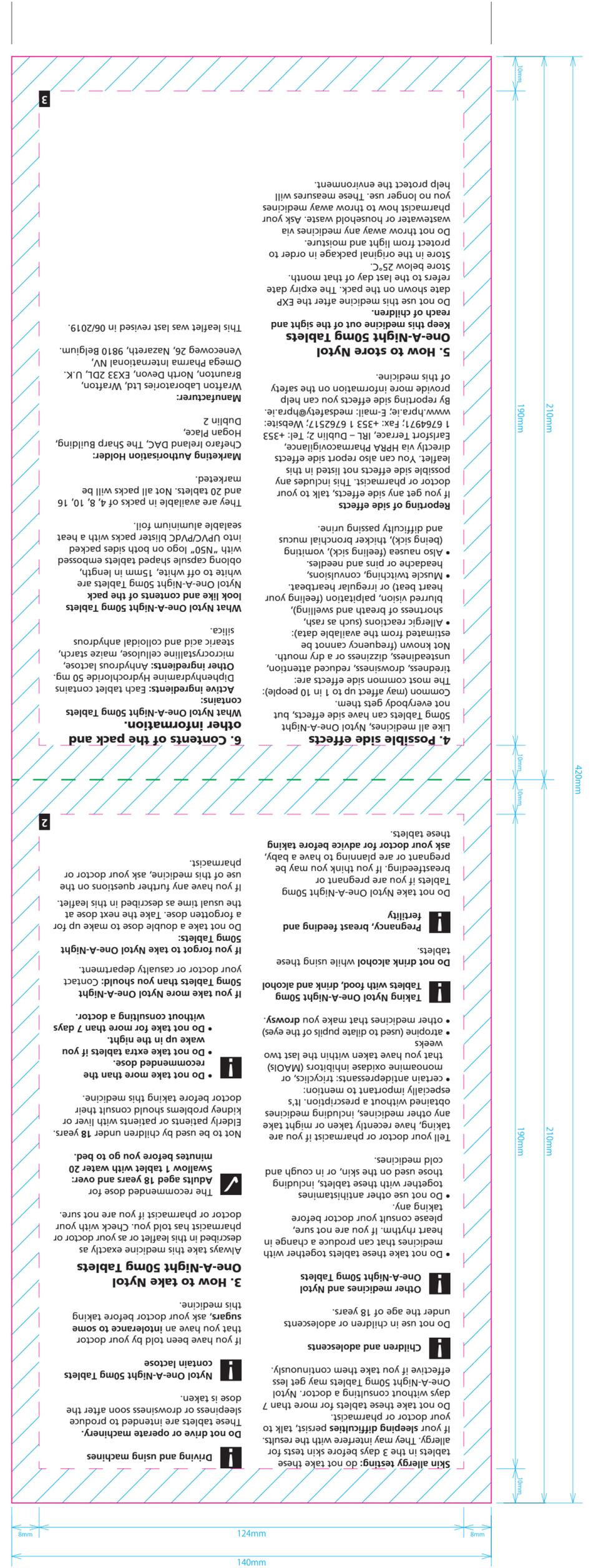
Do not take these tablets:

- 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 Pheochromocytoma
- 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.



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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
Do not use other antihistamines together with these tablets, including cold medicines.

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.

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.

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.

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 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. 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.

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: Drowsiness, reduced attention, tiredness, dizziness, a dry mouth, unsteadiness, diarrhoea 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. 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.

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. 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.

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 HPA Pharmacovigilance, Earlsfort Terrace, RII – Dublin 2. Tel: +353 1 6762517; 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. 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 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.

Manufacture: Wafaton Laboratories Ltd, Wafaton, Brantton, North Devon, EX33 2DL, U.K. **Marketing Authorisation Holder:** Chexan Ireland DAC, The Sharp Building, Dublin 2. **Manufacturer:** Omega Pharma International NV, Venecoweg 26, Nazareth, 9810 Belgium. This leaflet was last revised in 06/2019.

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.

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 after 7 days.

What is in this leaflet

1. What Nytol One-A-Night 50mg Tablets are and what are they used for
2. What you need to know before you take Nytol One-A-Night 50mg Tablets
3. How to take Nytol One-A-Night 50mg Tablets
4. Possible side effects
5. How to store Nytol One-A-Night 50mg Tablets
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 to 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 take 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 used within the last two weeks
- atropine (used to dilate pupils of the eyes)
- medicines which 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 breast-feeding. 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 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 50mg Tablets

[For medicines available without prescription]:

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 forget 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 HPRC 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 packaging 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
The Sharp Building,
Hogan Place,
Dublin 2

Manufacturer

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

Omega Pharma International NV, Venecoweg 26, Nazareth, 9810 Belgium

This medicinal product is authorised in the Member States of the EEA under the following names:

Country	Product Name
UK (RMS)	Diphenhydramine 50mg Tablets
Austria	Diphenhydramine Omega Pharma 50mg Tablets
Belgium	Diphenhydramine Hydrochloride Omega Pharma 50mg Tablets
France	Chlorhydrate de diphenhydramine Omega Pharma 50 mg, comprimé
Ireland	Nytol One-A-Night 50mg Tablets
Poland	Nytol Sen
Portugal	Diphenhydramine Omega Pharma 50mg Tablets
Spain	Difenhidramina Omega-Pharma 50mg comprimidos

This leaflet was last revised in 06/2019.