



Package leaflet: Information for the user

## Nytol Liquid Caramel Flavour 10mg/5ml oral solution

### Diphenhydramine Hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you. Always use 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 or pharmacist if you do not feel better or if you feel worse after 14 days.

#### What is in this leaflet

- What Nytol Liquid Caramel Flavour 10mg/5ml oral solution is and what it is used for?
- What you need to know before you use Nytol Liquid Caramel Flavour 10mg/5ml oral solution
- How to use Nytol Liquid Caramel Flavour 10mg/5ml oral solution
- Possible side effects
- How to store Nytol Liquid Caramel Flavour 10mg/5ml oral solution
- Contents of the pack and other information

#### 1. What Nytol Liquid Caramel Flavour 10mg/5ml oral solution is and what it is used for?

This medicine contains the following active ingredient: **Diphenhydramine hydrochloride**. Diphenhydramine hydrochloride is an antihistamine which works by blocking the body's response to histamine. Histamine is involved in the brain's waking system so diphenhydramine hydrochloride can help alleviate temporary sleeplessness.

#### 2. What you need to know before you use Nytol Liquid Caramel Flavour 10mg/5ml oral solution



##### Do not use this medicine

- if you are allergic to diphenhydramine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you have a peptic ulcer narrowing the stomach or the duodenum
- if you have a blockage between your stomach and small intestine.
- if you know you have a problem with 'QT interval prolongation' (a measure of the heart's electrical activity)
- if you are at risk for QT interval prolongation (a measure of the heart's electrical activity) incl. a known cardiovascular disease, imbalance of potassium or magnesium, family history of sudden cardiac death, slow heart rate, concomitant use with medicines known to prolong the QT interval and/or induce Torsade de Pointes (abnormal electrical activity in the heart with life-threatening rhythm disturbance)
- In children under 16 years of age

#### Warnings and precautions

- Talk to your doctor or pharmacist before taking this medicine:
- if you suffer from myasthenia gravis (a disease, causing muscle weakness)
  - if you suffer from seizures or have epilepsy
  - if you suffer from asthma, bronchitis or Chronic Obstructive Pulmonary Disease (COPD)
  - if you have damage to the nerve in the eye caused by pressure inside the eye rising rapidly because fluid cannot drain out (narrow-angle glaucoma)
  - if you have an enlarged prostate
  - if you have inability to completely empty the bladder
  - if you have moderate to severe liver or kidney problems
  - if you are elderly, particularly in elderly who also suffer from confusion.
  - if you have restless leg syndrome (a disorder where the patient has uncontrollable urges to move the legs to stop uncomfortable, painful or odd sensations, usually at night)
- Tolerance may develop with continuous use. Do not take this medicine for more than 14 days without consulting a doctor.
- This medicine is for short term use. It may not work as well if you use it continuously. If your symptoms persist, see your doctor for advice.

Cases of dependence and / or abuse have been reported in young people and in patients with psychiatric disorders and / history of abuse disorder. Signs of this occurring should be reported to a doctor.

**Skin allergy testing:** do not take this medicine several days before skin tests for allergy. They may interfere with the results

Avoid the use of other antihistamines including those used on your skin and in cough and cold medicines.

Do not use to sedate a child.

#### Other medicines and Nytol Liquid Caramel Flavour 10mg/5ml oral solution:

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including:
- Tranquillisers or anxiolytics (sedatives) used to treat anxiety e.g. diazepam
  - Hypnotics (e.g. nitrazepam) used to help you sleep better
  - Monoamine oxidase inhibitors (MAOIs) for depression (e.g. phenelzine) or if you have taken or stopped taking an MAOI within the last two weeks.
  - Metoprolol (a beta blocker) used to treat high blood pressure, angina, irregular heart beat or overactive thyroid
  - Venlafaxine used to treat depression
  - Anticholinergics which relax smooth muscle and are used for example in Parkinson's disease, irritable bowel syndrome and incontinence e.g. procyclidine, trihexyphenidyl, atropine, oxybutynin, fesoterodine
  - medicines that prolong the QT interval (e.g. antiarrhythmics such as quinidine, sotalol, amiodarone)
  - Tricyclic antidepressants (e.g. imipramine, amitriptyline).

#### Nytol Liquid Caramel Flavour 10mg/5ml oral solution with alcohol:

While taking this medicine avoid alcoholic drink.

#### Pregnancy and breast-feeding

Do not take this medicine if you are planning to have a baby, if you are pregnant or breast-feeding without consulting a doctor first.

#### Driving and using machines

This medicine causes drowsiness and sedation and may also cause dizziness, blurred vision, disturbance in attention and slower reaction times. Do not drive or operate machinery while you are affected in this way.

#### Important information about some of the ingredients in Nytol Liquid Caramel Flavour 10mg/5ml oral solution

In addition to the active ingredient, some of the other ingredients in this medicine may affect some individuals:

- This medicine contains 1.66g of sucrose in 5ml. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product
- This medicine contains 260mg propylene glycol in each 5ml.

- This medicine contains Parahydroxybenzoates (methyl E218, ethyl E214, propyl E216 & butyl) which may cause allergic reactions (possibly delayed).
- This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.

#### 3. How to use Nytol Liquid Caramel Flavour 10mg/5ml oral solution

Always use 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 is:

##### Adults:

10 to 25ml to be taken at bedtime or after retiring when sleep is not readily achieved. Do not exceed the stated dose or frequency of dosing.

Not recommended as a sleep aid in children or adolescents under 16 years of age. Do not take for more than 2 weeks without consulting a doctor.

#### If you take more Nytol Liquid Caramel Flavour 10mg/5ml oral solution than you should:

Seek medical attention as soon as possible. When seeking medical advice you should, if possible, take the medicine and this leaflet with you provided it doesn't cause a delay. 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 you experience any of the following, STOP USING THIS MEDICINE IMMEDIATELY and SEEK IMMEDIATE MEDICAL ADVICE, as these may be signs of an allergic reaction:

- Difficulty breathing or shortness of breath
- Swelling of skin or mucous membrane, face, tongue and throat causing breathing difficulties, rash, hive (itchy, raised red weals)

If you experience any of the following, stop using the medicine and talk to your doctor straightaway:

- Convulsions (episodes of spasm(s) and reduced consciousness), difficulty making or controlling movements.
- Feeling that your heart is beating more rapidly, strongly or irregularly.

#### 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, disturbance in attention
- Dry mouth
- Fatigue.

##### Other side effects (frequency not known – cannot be estimated from the data available):

- Headache
- Sensations like tingling or numbness (pins and needles)
- Localized numbness
- Depression
- Sleep disturbances
- Confusion, excitation e.g. increased energy, restlessness, nervousness (the elderly are more likely to experience these effects)
- Difficulty urinating or inability to completely empty the bladder
- Thicker bronchial mucus
- Blurred vision
- Feeling or being sick, stomach problems
- Muscle twitching
- An irresistible urge to move your legs to stop uncomfortable, painful or odd sensations, usually at night (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](http://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 Liquid Caramel Flavour 10mg/5ml oral solution

Keep this medicine out of the sight and reach of children. Store below 25°C. Do not use this medicine after the expiry date which is stated on the carton and bottle label. The expiry date refers to the last day of that month.

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 this medicine contains:

The active substance is diphenhydramine hydrochloride, 10mg in 5ml. The other ingredients are: purified water, sucrose, sodium saccharin, propylene glycol, glycerin, parahydroxybenzoates (methyl E218, ethyl E214, propyl E216 & butyl), caramel flavouring, colouring (caramel E150).

##### What Nytol Liquid Caramel Flavour 10mg/5ml oral solution looks like and the contents of the pack:

Nytol Liquid Caramel Flavour 10mg/5ml oral solution is a caramel coloured oral solution supplied in glass bottles of 300ml, 150ml and 100ml. Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer:

The marketing authorisation holder is: Omega Pharma Ltd Wrafton, Braunton, Devon, EX33 2DL, United Kingdom

The EEA site of batch release is: Laleham Health and Beauty Limited, Greenhalgh, Preston, PR4 3JA, UK.

This leaflet was last revised in May 2025.

PL02855/0313

LF22058F

LF000841