

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 your symptoms worsen or do not improve*

This leaflet contains the following information.

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

1. What Nytol Liquid Caramel Flavour 10mg/5ml oral solution is and what is it 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 do 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 ingredients listed in **section 6** of this leaflet
- if you have a peptic ulcer
- if you have a blockage between your stomach and small intestine.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

- if you suffer from myasthenia gravis (abnormal muscle function)
- if you suffer from seizures or have epilepsy
- if you suffer from asthma, bronchitis or Chronic Obstructive Pulmonary Disease (COPD)
- if you have narrow-angle glaucoma
- if you have an enlarged prostate
- if you have difficulty urinating
- if you have moderate to severe liver or kidney problems
- if you are elderly, particularly if you also suffer from confusion.

Do not use to sedate a child.

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.

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:

- Other antihistamines including those used on your skin and in cough and cold medicines
- Tranquilisers 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 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
- 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 pregnant or breast-feeding.

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 take a repeat dose in the same night.

Not recommended as a sleep aid in children under 16 years of age.

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 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, disturbance, 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)
- 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 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 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
32 Vauxhall Bridge Road
London
SW1V 2SA

The EEA site of batch release is:

Laleham Health and Beauty Limited,
Greenhalgh, Preston, PR4 3JA, UK.

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