

# Numark Night Time Sleep Aid Tablets

## Diphenhydramine Hydrochloride

H0123-4

**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 Night Time Sleep Aid Tablets are and what are they used for?
2. What you need to know before you use Night Time Sleep Aid Tablets
3. How to use Night Time Sleep Aid Tablets
4. Possible side effects
5. How to store Night Time Sleep Aid Tablets
6. Contents of the pack and other information

## 1. What Night Time Sleep Aid Tablets are and what are they used for?

Night Time Sleep Aid Tablets contain the following active ingredient: **Diphenhydramine hydrochloride**. Diphenhydramine hydrochloride is an antihistamine which works by blocking the body's response to histamine, which is an agent responsible for causing allergic responses such as hay fever, stings and rashes. Histamine is also involved in the brain's waking system so diphenhydramine hydrochloride can help alleviate temporary sleeplessness.

## 2. What you need to know before you use Night Time Sleep Aid Tablets

### Do not use Night Time Sleep Aid Tablets:

- 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 Night Time Sleep Aid Tablets:

- if you suffer from myasthenia gravis (abnormal muscle function)
- if you suffer from seizures or have epilepsy
- if you have 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.

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 Night Time Sleep Aid Tablets:

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
- 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 stopped taking an MOAI 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 muscles 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).

## Night Time Sleep Aid Tablets with alcohol:

While taking Night Time Sleep Aid Tablets avoid alcoholic drink.

## Pregnancy and breast-feeding:

Do not take Night Time Sleep Aid Tablets 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.

## Night Time Sleep Aid Tablets contain lactose and sucrose:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### 3. How to use Night Time Sleep Aid Tablets

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:

#### For use as a temporary sleep aid:

**Adults:** 1 or 2 tablets 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.

#### For the treatment of hay fever, stings, rashes and other minor allergies:

**Adults and children over 12 years:** 1 or 2 tablets three or four times a day or as prescribed by a doctor.

Not recommended for children under 12 years of age.

#### If you take more Night Time Sleep Aid Tablets 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 the tablets 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 other effects:**

**Common effects (may affect up to 1 in 10 people):**

- Sedation, drowsiness, dizziness, unsteadiness, disturbance, inattention
- Dry mouth
- Fatigue.

**Other 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.

#### 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 the 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 Night Time Sleep Aid Tablets

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 blister pack. 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 Night Time Sleep Aid Tablets contain:

The active substance is diphenhydramine hydrochloride, 25mg. The other ingredients are: lactose, corn starch, povidone, magnesium stearate, Opaseal (polyvinyl acetate phthalate, ethyl acetate and stearic acid), sucrose, calcium carbonate, talc, acacia, titanium dioxide E171, Opalux Pink AS 1537 (E127 erythrosine), Opaglos 6000 (carnauba wax, beeswax), silicone fluid.

#### What Night Time Sleep Aid Tablets look like and the contents of the pack:

Night Time Sleep Aid Tablets are pink, sugar coated, tablets and are supplied in packs of 8, 16 or 20 tablets. Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer:

The marketing authorisation holder is:

Norma Chemicals Ltd.,  
51-53 Stert Street, Abingdon,  
Oxfordshire, OX14 3JF, UK.

The EEA site of batch release is:

Surepharm Services Ltd.,  
Bretby Business Park,  
Burton upon Trent, DE15 0YZ, UK.

or

Wasdell Packaging Ltd.,  
Euroway Industrial Estate,  
Blagrove, Swindon, Wiltshire, SN5 8YW, UK

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