139.7 mm

228.6 mm

Package leaflet: Information for the user

Boots Sleepeaze

50 mg 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.

In this leaflet:

1. What Sleepeaze 50 mg Tablets are and what they are used for
2. What you need to know before you take Sleepeaze 50 mg Tablets
3. How to take Sleepeaze 50 mg Tablets
4. Possible side effects
5. How to store Sleepeaze 50 mg Tablets
6. Contents of the pack and other information

1. What Sleepeaze 50 mg Tablets are and what they are used for

Sleepeaze 50 mg 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, this medicine has been shown to help sufferers to fall asleep faster, have a longer and deeper sleep, and to wake up feeling rested in the morning.

Do not take this medicine for more than 2 weeks without consulting your doctor.

2. What you need to know before you take Sleepeaze 50 mg Tablets

Do not take this medicine:
- **if you have ever had an allergic reaction** to diphenhydramine hydrochloride or 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).

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine:
- 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 **myasthenia gravis, epilepsy** or **seizure disorders**
- If your **sleeping difficulties** persist, talk to your doctor or pharmacist
- Stop taking Sleepeaze 50mg Tablets at least 3 days before any allergy skin testing, as it may interfere with the results.
- This medicine may get less effective if you use it continuously.

Other medicines and Sleepeaze 50 mg Tablets
Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed medicines; particularly **tricyclic antidepressants, monoamine oxidase inhibitors** (MAOIs prescribed for **depression**) within the last two weeks, atropine (used to dilate pupils of the eyes) or medicines which make you **drowsy**. Do not take Sleepeaze 50mg Tablets together with medicines that can produce a change in heart rhythm called QT prolongation which is seen by electrocardiogram (ECG). If you are not sure, please consult your doctor before taking this medicine. Avoid the use of **other antihistamines** including those used on your skin and in cold and cough medicines, while taking this medicine.

Sleepeaze 50 mg Tablets with food, drink and alcohol
Do not drink alcohol while using this medicine.

Pregnancy, breast-feeding and fertility
Talk to your doctor before taking this medicine if you are pregnant, trying to become pregnant, or breast-feeding.

Driving and using machines
Do not drive or operate machinery. This medicine is intended to produce sleepiness or drowsiness soon after the dose is taken.

Sleepeaze 50 mg 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 Sleepeaze 50 mg 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 and children aged 16 years and over: Swallow 1 tablet with water 20 minutes before you go to bed.

Not to be used by children under 16 years. Not to be used by the elderly with confusion.

- **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 2 weeks without consulting a doctor.**

If you take more Sleepeaze 50 mg Tablets than you should
Contact your doctor or casualty department.

If you forget to take Sleepeaze 50 mg 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, 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, hives (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, 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)
- 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, 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 Sleepeaze 50 mg Tablets
Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date (EXP) stated on the pack.
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.
Store below 25 °C.

6. Contents of the pack and other information
What Sleepeaze 50 mg Tablets contain
- The active substance: Each tablet contains Diphenhydramine Hydrochloride 50 mg.
- The other ingredients are: Anhydrous lactose, microcrystalline cellulose, maize starch, stearic acid and silicon dioxide.

What Sleepeaze 50 mg Tablets look like and contents of the pack
Packs of Sleepeaze 50 mg Tablets contain 4, 8, 10, 16 or 20 tablets. Not all pack sizes may be marketed.

Marketing authorisation holder is Omega Pharma Ltd., Wrafton, Braunton, Devon, EX33 2DL, United Kingdom and all enquiries should be sent to this address.

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

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