

Patient Information Leaflet - Information for the user

Boots Pharmaceuticals logo

Sleepeaze 50 mg Tablets (Diphenhydramine Hydrochloride)

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription to treat minor conditions. However, you still need to take it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice

What this medicine is for

This medicine contains Diphenhydramine Hydrochloride which belongs to a group of medicines called sedating antihistamines, which help you to sleep. It can be used to relieve short term sleeplessness.

Before you take this medicine

This medicine can be taken by adults and children aged 16 years and over. However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first.

X Do not take:

- **If you are allergic** to any of the ingredients
- **If you have asthma**
- **If you have narrow angle glaucoma** (sudden high pressure in the eye)
- **If you have a stomach ulcer** or obstruction of the gut or bladder
- **If you have porphyria** (a rare blood disease)
- **If you have an intolerance to some sugars**, unless your doctor tells you to (this medicine contains lactose)
- **If you are pregnant or breastfeeding**
- **If you have an enlarged prostate or urinary retention**

! Talk to your pharmacist or doctor:

- If you have liver problems
- If you have long-term lung problems or difficulty breathing due to bronchitis (a condition which produces a lot of phlegm on the chest)
- If you have other forms of glaucoma (see above)
- If you have difficulty passing urine
- If you suffer from fits
- If you have a condition called myasthenia gravis
- If you have a condition called tinnitus, which causes ringing in the ears – the medicine may make it worse

Other important information

Driving and using machines: This medicine causes drowsiness. You should not drive or operate machinery for at least 8 hours after taking the tablet.

Do not drink alcohol (wine, beer, spirits) whilst taking this medicine.

If you take this medicine continuously for a long time (e.g. more than 2 weeks), you may become dependent on it.

If you take other medicines

Do not take this medicine, unless your doctor tells you to, if you are taking any of the following medicines:

- Monoamine oxidase inhibitors (for depression), or if you have taken them in the last 14 days
- Other depressant medicines (e.g. hypnotics, sedatives, tranquillisers, tricyclic antidepressants)
- Atropine

Tell your pharmacist about ANY other medicines you are using that are prescribed by your doctor, or bought for yourself, including herbal and homeopathic remedies, particularly the following:

- Medicines called Beta-blockers (usually for heart problems)
- Other medicines for depression

✓ How to take this medicine

Check the foil is not broken before use. If it is, do not take that tablet.

Age	How many to take	How often to take it
Adults and children of 16 years and over	One	20 minutes before going to bed. Don't take a second tablet in the same night.

Swallow the tablet with water.

Do not give to children under 16 years.

Not to be used by the elderly with confusion.

Do not take more than the amount recommended above.

If symptoms do not go away talk to your doctor.

! If you take too many tablets: Talk to a doctor straight away. Take your medicine and this leaflet with you.

Possible side effects

Most people will not have problems, but some may get some. If you are elderly you may be more likely to get some of these side effects.

! If you get any of these serious side effects, stop taking the tablets.

See a doctor at once:

- Difficulty breathing, swelling of the face, neck, tongue or throat (severe allergic reactions)

If you get any of the following side effects see your pharmacist or doctor:

- Blurred vision, dizziness, drowsiness, grogginess (these usually wear off about 8 hours after taking the tablet)
- Dry mouth, feeling sick, difficulty in passing urine
- Headache, difficulty in co-ordinating movement
- Stomach problems, liver problems, being sick
- Low blood pressure, fast, slow or irregular heart beat
- Skin rash
- Sleep disturbances, tremor, fits, sweating, confusion, depression, nervousness
- Feeling restless or excitable, lack of attention, increased energy, reduced sense of touch or sensation
- Raised, red, itchy skin
- Phlegm on the chest which may be harder to clear
- Ringing in the ears
- Muscle pain and stiffness, pins and needles, muscle twitching, feeling unsteady

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. By reporting side effects you can help provide more information on the safety of this medicine.

How to store this medicine

Do not store above 25°C.

Store in the original package. Keep the foil in the outer carton.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

Use by the date on the end flap of the carton.

What is in this medicine

Each tablet for oral administration contains Diphenhydramine Hydrochloride 50 mg, which is the active ingredient.

As well as the active ingredient, the tablets also contain lactose, maize starch, magnesium stearate.

The pack contains 20 tablets.

Who makes this medicine

Manufactured for The Boots Company PLC Nottingham NG2 3AA by Galpharm International Ltd Elmhirst Park Middle Field Road Barnsley South Yorkshire S75 4LS UK. Marketing Authorisation held by Galpharm Healthcare Ltd Wrafton Braunton Devon EX33 2DL UK.

Leaflet prepared September 2015

If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA.

Useful guidelines for a better night's sleep

In addition to Boots Sleepeaze 50 mg Tablets, the following guidelines may enhance your sleep pattern and help you enjoy the benefits of a good night's sleep.

1. Relax, switch off and unwind from the day. Try to forget the trials and tribulations of the day.
2. Before retiring to bed listen to music, read a book or exercise gently to clear your mind from the day's stresses. Strenuous exercise should be undertaken earlier on in the day, as this stimulates a rush of adrenaline which may keep you awake.
3. Try to avoid dozing in front of the TV, save your sleep for bedtime. If your dozing is boredom, why not take up an alternative relaxing activity.
4. Do not drink tea or other caffeinated drinks before bedtime, as these will encourage you to visit the lavatory. A hot milky drink or barley water are more suitable.
5. Avoid stimulants such as alcohol and nicotine. It is also advisable to eat before 8 pm, if possible, and avoid fatty foods.

6. Ensure your bed and bedroom are comfortable, not too hot or cold and your room is quiet and dark. Remove all temptations, such as work material from your room.
7. Get into a routine. Experiment by going to bed at the same time and note what time you wake up each day for a week and so identify how many hours sleep you need and adjust these times accordingly.
8. Be patient. An adequate sleep pattern may take some time to establish.

Other formats

To request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name: Boots Sleepeaze 50 mg Tablets

Reference number: PL 16028/0010

This is a service provided by the Royal National Institute of Blind People.

Artwork reference BTC205086 action B