Patient Package Insert in Accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine can be sold without a physician's prescription

Sleep Aid

Tablets

Active ingredient and its quantity:
Each tablet contains doxylamine succinate 25 mg

For a list of inactive ingredients in the product - see section 6 and section 2 "Important information about some of the ingredients of this medicine" in this leaflet.

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the physician or pharmacist.

Take this product according to the instructions in the dosage section in this leaflet. Consult the pharmacist if you need additional information.

If insomnia continues for more than ten consecutive days despite using this medicine, stop using the medicine and refer to the physician. Insomnia may be a symptom of another underlying disease.

The medicine is not intended for children under the age of 12 years. Below this age contact the physician.

1. What is the medicine intended for?

Sleep Aid is intended as an aid for the relief of temporary sleep disturbance.

Therapeutic group: Antihistamines.

The mechanism of action of this medicine: Blocking the action of histamine and other substances produced by the body to provide relief from allergic symptoms. In addition, this medicine slows down the activity of the central nervous system, which relieves insomnia.

There is no evidence that this medicine is addictive.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient doxylamine succinate or to any of the other ingredients this medicine contains (see section 6 "Additional information"). Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or skin hives; fainting or hay fever-like symptoms. If you think you are having an allergic reaction, stop taking the medicine and refer immediately to a doctor or to the emergency room of the nearest hospital.
- You have or have had breathing problems such as: asthma or chronic bronchitis.
- You have or have had a severe liver or kidney disease.
- You have or have had closed-angle glaucoma.
- You have or have had problems in the prostate.
- You have or have had difficulty urinating.
- You have or have had a narrowing or blockage between the stomach and the small intestine which causes vomiting of undigested food.
- You have or have had epilepsy.

Special warnings regarding the use of the medicine:

Before the treatment with Sleep Aid, tell the physician if:

You are pregnant, breastfeeding or planning to become pregnant (see Section 2 "Pregnancy, breastfeeding and fertility").

Drug interactions

If you are taking or have recently taken other medicines including non-prescription medicines and nutritional supplements, tell the physician or pharmacist. Especially inform the doctor or pharmacist if you are taking:

- Antidepressants of the monoamine oxidase inhibitors group (MAO inhibitors), such as: moclobemide, phenelzine, tranylcypromine.
- Tricyclic antidepressants, such as: amitriptyline, imipramine, nortriptyline, doxepin.
- Strong analgesics, such as: codeine, morphine.
- Other medicines that help sleeping, such as: temazepam, triazolam or nitrazepam.
- Medicines for treatment of anxiety, such as: oxazepam, diazepam.
- Aminoglycoside antibiotics, such as: tobramycin.

Use of this medicine and alcohol consumption

Be careful when drinking alcohol (wine and other alcoholic beverages) during treatment with this medicine. The effects of alcohol may be more severe when combined with antihistamine medicines such as Sleep Aid.

Pregnancy, breastfeeding and fertility

Consult with the doctor or pharmacist if you are pregnant or planning to become pregnant. There is no evidence that this medicine causes congenital malformations, but no studies that prove the safety of this medicine for the development of the fetus have been conducted.

Consult with the doctor or pharmacist if you are breastfeeding or planning to breastfeed. Small amounts of the medicine pass into breastmilk. It is possible that the breastfed infant will become unusually irritable or excited. Moreover, the medicine may affect breastmilk production.

Driving and using machines

Exercise caution when driving a car, operating dangerous machinery and during any activity that requires alertness while using the medicine, because using **Sleep Aid** may impair alertness on the day after taking the medicine.

Important information about some of the ingredients of this medicine

Sleep Aid contains less than 23 mg of sodium per tablet, and is therefore considered sodium-free.

3. How to use the medicine

Check with the physician or pharmacist if you are not sure about the dosage and the treatment regimen of the product.

The usual recommended dosage for adults and children 12 years of age and older is: half a tablet to one tablet, about half an hour before bedtime.

This medicine is not intended for infants and children under 12 years of age.

Do not exceed the recommended dose.

Duration of treatment

Do not use Sleep Aid for more than ten consecutive days. If the sleeping disturbance persists for more than ten days, refer to the physician.

Method of administration

Swallow the tablet with water. The medicine may be taken with food.

Take Sleep Aid only before bedtime.

Take out the tablet by peeling the foil seal on the corner of the blister, where the words PELL&PUSH are printed. Do not forcefully push the tablet through the foil seal, because the tablet might break.

Crushing/halving/chewing

The tablet can be halved.

There is no information on crushing/chewing the tablet.

If you have accidentally taken a higher dosage, you may feel:

- Severe drowsiness
- Severe dryness of the mouth, nose and throat
- Redness of the face
- Fast, throbbing or irregular heartbeats
- Shortness of breath
- Hallucinations
- Convulsions, spasms
- Insomnia
- Dilated pupils

If you have taken an overdose or if a child has accidentally swallowed this medicine, proceed immediately to a physician or to a hospital emergency room and bring the medicine package with you.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the physician or pharmacist.

4. Side effects

As with any medicine, the use of **Sleep Aid** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

If you are over the age of 65 years, your chance of experiencing side effects may increase.

The following side effects are more common. Usually they are mild and pass after a short time:

- Drowsiness on the day after using the medicine
- Dizziness
- Lack of coordination
- Dry mouth, nose and/or throat
- Headache
- Muscle weakness
- Viscous runny nose

Severe side effects are rare.

Refer to a physician as soon as possible if you suffer from:

- Fast, throbbing or irregular heartbeats
- Low blood pressure
- Difficulty urinating
- Constipation
- Chills
- Nervousness
- irritability
- Excitability
- Fainting
- Blurred vision
- Increased gastric reflux

If a side effect appears, if one side effect gets worse or if you suffer from a side effect which is not mentioned in this leaflet, consult the physician.

Reporting of side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects from Drug Treatment" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or by clicking on the following link: https://sideeffects.health.gov.il

Additionally, side effects can be reported to Padagis via the following address: Padagis.co.il

5. How to store the medicine

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25ºC.

6. Additional information

- **In addition to the active ingredient, the medicine also contains:** Microcrystalline Cellulose, Anhydrous Dibasic Calcium Phosphate, Dibasic Calcium Phosphate Dihydrate, Sodium Starch Glycolate, Magnesium Stearate, FD&C Blue #1 Aluminium Lake.
- **What does the medicine look like and what is the content of the package:** A light blue, oval tablet with a score line on one side and "L441" imprinted on the other side. The tablets are packed in a blister pack containing 16 tablets.
- **Registration holder name and address:** Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.
- **Manufacturer name and address:** Perrigo, Allegan, Michigan, USA.
- Revised in May 2023 according to MOH guidelines.
- **Registration number of the medicine at the National Drug Registry of the Ministry of Health:** 131-07-30938.

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