

**PATIENT LEAFLET IN ACCORDANCE
WITH THE PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

This medicine is dispensed without a doctor's prescription



Tonight tablets 25 mg

Each tablet contains 25 mg Doxylamine Succinate

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

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

Take the product according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you have further questions. If the insomnia persists for more than ten consecutive days despite using this medicine, stop using the medicine and refer to the doctor. The insomnia may be a symptom of another underlying disease.

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

1. What is the medicine intended for?

This medicine is indicated as an aid for relief of temporary sleep disorder.

Therapeutic class: anti-histamines.

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 this medicine if:

- You are sensitive (allergic) to the active ingredient doxylamine succinate or to any of the additional components this medicine contains (see section 6). Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or breathing difficulty; 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 treatment with Tonight, inform the doctor if:

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

⚠ Drug-drug interactions:

If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell the doctor or the 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 the medicine and alcohol consumption:

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

⚠ 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 operating machinery:

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

⚠ Important information about some ingredients of the medicine:

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

3. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The usually accepted 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 this medicine for more than 10 consecutive days. If the sleeping disturbance persists for more than 10 days, refer to the doctor.

Method of administration

The medicine should be taken with water. The medicine may be taken with food.

Take this medicine only before bedtime.

Crushing/halving/chewing

Do not chew, the tablet is intended to be swallowed.

The tablet can be halved. If necessary, the tablet may be crushed.

If you accidentally took 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 (dyspnea)
- Hallucinations
- Convulsions, spasms
- Insomnia
- Dilated pupils

If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

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

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

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

If you are above the age of 65, your chance of experiencing side effects may be increased.

The following are the more common side effects, which are usually moderate and resolve after a short time:

- Drowsiness on the day after taking the medicine
- Dizziness
- Lack of coordination
- Dryness of the mouth, nose and/or throat
- Headache
- Muscle weakness
- Viscous nasal mucus

Severe side effects are rare.

Tell the doctor as soon as possible if you suffer from:

- Fast, throbbing or irregular heartbeats
- Low blood pressure
- Difficulty urinating
- Constipation
- Chills
- Nervousness
- Irritability
- Excitability
- Fainting
- Blurry vision
- Increased gastroesophageal reflux

If a side effect occurs, or if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

- Do not use the medicine after the expiry date (EXP) appearing on the package. The expiry date refers to the last day of that month.
- Store at a temperature lower than 25°C.

6. Additional information:

In addition to the active ingredient, the medicine also contains: Microcrystalline Cellulose, Dibasic Calcium Phosphate Dihydrate, Sodium Starch Glycolate, Magnesium Stearate.

What does the medicine look like and what are the contents of the package: Oval cream-white tablet, with a score line on one side.

The medicine is supplied in a blister package containing 2, 5 or 10 tablets. Not all package sizes may be marketed.

Manufacturer/license holder and address:

CTS Chemical Industries Ltd., 3 Hakidma st., P.O. box 385, Kiryat Malachi, Israel.

This leaflet was revised in 12/2021 in accordance with the Ministry of Health instructions.

Registration number of the medicine in the national drug registry of the Ministry of Health: 118-20-29793-00.

