

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

The medicine is dispensed with a doctor's prescription only

Melatonin Inovamed 2 mg

Prolonged-release tablets

Active ingredient:

Each tablet contains 2 mg melatonin

Inactive ingredients and allergens in the preparation: see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

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

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

The medicine is intended for adults over the age of 55.

1. What is the medicine intended for?

Melatonin, the active ingredient in Melatonin Inovamed 2 mg, belongs to a group of natural hormones produced by the body.

Melatonin Inovamed 2 mg is used for a short-term treatment of primary insomnia (sleeplessness, difficulty falling asleep or staying asleep or poor quality of sleep), in patients aged 55 and over. Insomnia is defined as 'primary' when it is not the result of an identified cause, such as a medical, mental or environmental condition.

Therapeutic class: a hormone secreted by the body.

2. Before using the medicine

Do not use this medicine if:

You are sensitive (allergic) to the active ingredient melatonin or to any of the additional components the medicine contains (for a list of inactive ingredients please see section 6 "Additional information". In addition, see in section 2 "Important information about some of the ingredients of the medicine").

Special warnings regarding the use of the medicine

Before treatment with Melatonin Inovamed 2 mg, inform the doctor if:

- You are pregnant or breastfeeding (see section "Pregnancy and breastfeeding").
- You suffer from liver or kidney problems. Using Melatonin Inovamed 2 mg is not recommended in these conditions, since no studies on Melatonin Inovamed 2 mg have been conducted in people with liver or kidney diseases.
- You suffer from intolerance to certain sugars.
- You suffer from an autoimmune disease (a disease in which the body is attacked by its own immune system).

Using Melatonin Inovamed 2 mg is not recommended in these conditions, since no studies on Melatonin Inovamed 2 mg have been conducted in people with autoimmune diseases.

Melatonin Inovamed 2 mg may cause sleepiness and therefore may impair your ability to perform any activity requiring alertness, such as driving (see section "Driving and operating machinery").

Smoking may reduce the effect of Melatonin Inovamed 2 mg, since ingredients in the tobacco smoke may increase the breakdown of melatonin in the liver.

Do not administer the medicine to children aged 0 to 18 years, since its effect on them has not been studied and is unknown.

Drug interactions

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

- Fluvoxamine (for treatment of depression and obsessive-compulsive disorder), psoralens (for treatment of skin problems such as psoriasis), cimetidine (for treatment of gastric ulcers), quinolone antibiotics and rifampicin (for treatment of bacterial infections), estrogens (found in contraceptive pills or in medicines for hormone replacement therapy) and carbamazepine (for treatment of epilepsy).
- Medicines belonging to the family of adrenergic agonists or antagonists such as certain medicines for regulating blood pressure by blood vessel contraction, medicines for reducing nasal congestion, medicines for lowering blood pressure; medicines belonging to the family of opiate agonists or antagonists such as medicines for treating narcotic addiction; prostaglandin inhibitors (such as non-steroidal anti-inflammatory drugs), antidepressants, tryptophan and alcohol.
- Benzodiazepines and other sleep-inducing medicines that do not belong to the benzodiazepines group, such as zaleplon, zolpidem and zopiclone.
- Thioridazine (for treatment of schizophrenia) and imipramine (for treatment of depression).

Use of the medicine and food

Melatonin Inovamed 2 mg should be taken after a meal.

Use of the medicine and alcohol consumption

Do not drink alcohol before, during or after taking Melatonin Inovamed 2 mg, since alcohol reduces the medicine's efficacy.

Pregnancy and breastfeeding

Do not use Melatonin Inovamed 2 mg if you are pregnant, think you are pregnant, are trying to become pregnant or breastfeeding.

Consult a doctor or pharmacist before using this medicine.

Driving and operating machinery

Melatonin Inovamed 2 mg may cause sleepiness. If this is how the medicine affects you, do not drive or operate dangerous machinery while using the medicine. If you suffer from persistent sleepiness, consult a doctor.

Important information about some of the ingredients of the medicine

Melatonin Inovamed 2 mg contains lactose monohydrate (a type of sugar), which may cause an allergic reaction in patients who are sensitive to lactose. If you have been told by the doctor that you have an intolerance to some sugars, consult the doctor before starting treatment with this medicine.

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The dosage and treatment regimen will be determined by the doctor only. The generally accepted dosage is:

One tablet per day (2 mg), after food, 1-2 hours before bedtime. You may continue this dosage for a period of up to 13 weeks. Consult the doctor if you do not feel better or if you feel worse after 21 days.

Do not exceed the recommended dose.

Method of use: do not chew! The medicine should be swallowed whole after a meal.

The tablet should not be halved or crushed.

If you accidentally took a higher dosage refer to a doctor or pharmacist as soon as possible.

Taking a higher dosage than recommended may make you feel groggy.

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

If you forgot to take the medicine, take the tablet as soon as you remember, before going to sleep, or at the usual time of the next dose, and then proceed as usual. Do not take a double dose.

Follow the treatment as recommended by the doctor.

If you stop taking the medicine: no harmful effect is known when treatment is discontinued suddenly or prematurely. There are no known withdrawal symptoms following end of treatment with Melatonin Inovamed 2 mg.

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

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

4. Side effects

As with any medicine, using Melatonin Inovamed 2 mg 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.

Stop use and refer immediately to the doctor if the following serious side effects appear:

Uncommon side effects – effects that occur in 1-10 users out of 1,000:

- Chest pain

Rare side effects – effects that occur in 1-10 users out of 10,000:

- Loss of consciousness or fainting
- Serious chest pain resulting from angina pectoris
- Palpitations
- Depression
- Visual disorders
- Blurred vision
- Disorientation
- Vertigo (dizziness)
- Presence of red blood cells in the urine
- Reduced amount of white blood cells in the blood
- Reduced amount of platelets in the blood, which increases the risk of bleeding or contusions
- Psoriasis

Refer to the doctor if the following non-serious side effects appear:

Uncommon side effects – effects that occur in 1-10 users out of 1,000:

Irritability, nervousness, restlessness, insomnia, abnormal dreams, nightmares, anxiety, migraines, headaches, exhaustion, psychomotor hyperactivity (restlessness accompanied by increased activity), dizziness, fatigue, hypertension, upper abdominal pain, digestive disorders, mouth ulceration, dry mouth, nausea, hyperbilirubinemia (a change in the composition of the blood which could cause yellowing of the skin or eyes), skin inflammation (dermatitis), night sweats, pruritus or skin rash, dry skin, limb pains, menopausal symptoms, weakness feeling, secretion of glucose or protein in the urine, abnormal results of liver function tests, weight increase.

Rare side effects – effects that occur in 1-10 users out of 10,000:

Shingles (herpes zoster, a viral disease), high level of lipids in the blood, low level of calcium in the blood, low level of sodium in the blood, mood swings, aggression, excitement, crying, stress symptoms, waking up early in the morning, increased libido, deteriorated mood, memory impairment, concentration disorders, dreaminess, restless legs syndrome, poor quality of sleep, pins and needles sensation, teary eyes, dizziness when standing up or sitting down, hot flashes, heartburn (reflux of acid from the stomach to the esophagus), gastrointestinal problems, mouth blisters, tongue ulceration, abdominal pain, vomiting, abnormal sounds from the digestive system, gastrointestinal flatulence, increased saliva secretion, bad breath, abdominal discomfort, stomach disorders, gastritis, eczema, skin rash, inflammation of the skin of the hands, itchy rash, nail problems, arthritis, muscle cramps, neck pain, muscle cramps at night, priapism that might be painful, prostate inflammation, fatigue, pain, thirst, passing a larger than usual volume of urine, night urination, increased liver enzymes, abnormal results of blood electrolytes and laboratory tests.

Side effects with unknown frequency (effects whose frequency has not yet been determined):

Hypersensitivity, swelling of the mouth or tongue, swelling of the skin and abnormal milk secretion.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your 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 must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package.

The expiry date refers to the last day of that month.

Storage conditions:

Store below 25°C. Keep in the original package to protect from light.

Do not discard medicines in wastewater or domestic trash. Ask the pharmacist how to discard an unneeded medicine, in order to protect the environment.

6. Additional information

In addition to the active ingredient the medicine also contains:

Lactose monohydrate, calcium hydrogen phosphate dihydrate, ammonio methacrylate copolymer (Type-B), talc, silica colloidal anhydrous, magnesium stearate.

What does the medicine look like and what are the contents of the package? White to off-white, round shaped biconvex tablet, plain on both sides.

Package type: the medicine is supplied in a carton package containing 30 tablets in trays (blisters).

License holder and importer: Inovamed Pharma Ltd., P.O. Box 2349, Bnei Brak.

Manufacturer: Aurobindo Pharma Ltd., Hyderabad, Telangana, India.

Revised in April 2025.

Registration number of the medicine in the national drug registry of the Ministry of Health: 178-95-38204