

Package leaflet: Information for the user

Melatonin Evolan 1 mg/ ml oral solution

melatonin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

1. What Melatonin Evolan is and what it is used for
2. What you need to know before you take Melatonin Evolan
3. How to take Melatonin Evolan
4. Possible side effects
5. How to store Melatonin Evolan
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1. What Melatonin Evolan is and what it is used for

Melatonin Evolan contains the active substance melatonin, which belongs to a group of natural hormones produced by the body. Melatonin helps regulate the body's day and night rhythm.

Melatonin Evolan can be used for:

- short-term treatment of jet lag in adults. Jet lag is characterized by sleep disturbances, daytime fatigue, exhaustion, mild cognitive symptoms, irritability and gastrointestinal disturbances after a flight.
- insomnia in children and adolescents aged 6-17 years with ADHD where other sleep-supporting measures has not worked well enough.

2. What you need to know before you take Melatonin Evolan

Do not take Melatonin Evolan

- if you are allergic to melatonin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Melatonin Evolan, if you have:

- epilepsy, as melatonin might increase or decrease the frequency of seizures.
- an autoimmune disease (where the body is 'attacked' by its own immune system).
- diabetes or impaired glucose tolerance, as this medicine may increase the level of glucose in your blood.
- impaired liver or kidney function.
- or if you are elderly.

- fertile women should use contraceptives during the Melatonin Evolan treatment, see “Pregnancy, fertility and breast-feeding” for more information.

Children under 6 years of age

Melatonin Evolan is not intended for children under 6 years of age.

Other medicines and Melatonin Evolan

Tell your doctor or pharmacist if you or your child is taking, has recently taken or might take any other medicines.

Melatonin Evolan may affect or be affected if taken at the same time as certain other medicines:

- fluvoxamine (used for the treatment of depression and obsessive-compulsive disorders)
- psoralens (used in the treatment of skin disorders e.g psoriasis)
- cimetidine (used in the treatment of stomach problems such as ulcers)
- estrogens (used in contraceptives or hormone replacement therapy)
- rifampicin (used in the treatment of tuberculosis)
- carbamazepine (used in the treatment of epilepsy)
- benzodiazepines and non-benzodiazepine hypnotics, such as zaleplon, zolpidem and zopiclone (used to induce sleep)
- warfarin (anticoagulants, treatment and prevention of blood clots)
- quinolones (e.g. ciprofloxacin and norfloxacin used in the treatment of bacterial infections)
- nifedipine or beta blockers (lower the blood pressure)
- NSAIDs (non-steroidal anti-inflammatory medicines), such as acetylsalicylic acid and ibuprofen (for pain and inflammation)

Caffeine

Caffeine can increase the effect of Melatonin Evolan since it can decrease the breakdown of melatonin by the liver.

Smoking

Smoking may reduce the effect of Melatonin Evolan since it can increase the breakdown of melatonin by the liver. Tell your doctor if you or your child smoke, start to smoke or quit smoking during treatment.

Melatonin Evolan with food, drink and alcohol

Do not drink alcohol before, during or after taking Melatonin Evolan, as alcohol can reduce the effect of melatonin on sleep.

Pregnancy, breast-feeding and fertility

If you or your child are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Contraceptives for fertile women and young girls

Fertile women and young girls should use contraceptives during the Melatonin Evolan treatment. Since this medicinal product may affect certain contraceptives (see “Other medicines and Melatonin Evolan”), the choice of contraceptive should be discussed with a doctor.

Pregnancy

Melatonin oral solution is not recommended if you or your child are pregnant. Melatonin crosses the placenta and there is insufficient information on the risk this may pose to the unborn child.

Breast-feeding

Melatonin oral solution is not recommended if you are breast-feeding. Melatonin is excreted in human milk, and a risk to the sucking child cannot be excluded.

Driving and using machines

Melatonin may cause drowsiness and may decrease alertness for several hours after intake. Therefore, this medicine should not be taken prior to driving or using machines.

Melatonin Evolan contains propylene glycol, benzyl alcohol and sodium

This medicine contains 52 mg propylene glycol in each ml and 6 mg benzyl alcohol in each ml. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially ‘sodium-free’.

3. How to take Melatonin Evolan

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults with jet lag

The recommended daily dose for adults and elderly is 1-5 ml (equivalent to 1-5 mg) and should be taken close to bedtime for 4-7 days. Maximum recommended daily dose is 5 ml (5 mg) if symptoms are not sufficiently relieved at lower doses.

The first dose should be taken after arrival at the destination, at your usual bedtime (in local time). Also on the following days, you should take the dose at the time you usually go to bed. Melatonin Evolan should not be taken before 20:00 or after 04:00 because then the desired effect may not be achieved.

A maximum of 16 treatment cycles of jet lag with Melatonin Evolan may occur per year.

Children and adolescents aged 6-17 years with ADHD with insomnia

Recommended dose: 1–2 ml (equivalent to 1–2 mg) 30–60 minutes before bedtime. If no improvement is seen in your/your child's symptoms, the doctor can increase the dose of Melatonin Evolan to find the most suitable dose for you/your child. The maximum daily dose that you/your child will receive is 5 ml (5 mg).

Treatment should be followed up regularly by a doctor (at least every 6 months is recommended) to see if it is still appropriate. The doctor should also regularly try to end the treatment (e.g. once a year) to ensure the correct medication.

How to take Melatonin Evolan

Melatonin Evolan should be swallowed.

A 5 ml dosing spoon graduated 1, 2, 3, 4 and 5 ml is included with the product.

Diabetes

If you or your child has diabetes or impaired glucose tolerance, no food should be consumed 2 hours before or after taking Melatonin Evolan (see "Warnings and precautions").

If you or your child takes more Melatonin Evolan than you/they should

If you or your child has taken too much medicine, or if for example a child has ingested the medicine by mistake, contact a doctor or hospital for assessment of the risk and advice.

The most common symptoms of overdose are drowsiness, headache, dizziness, and nausea.

If you or your child forget to take Melatonin Evolan

If you or your child forgets to take a dose at bedtime and wake during the night you may take the forgotten dose, but no later than 04:00 in the morning.

Do not take a double dose to make up for a forgotten dose.

If you or your child stop taking Melatonin Evolan

If you stop taking Melatonin Evolan, it will not cause any harmful effects or withdrawal symptoms.

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 you, or your child, experience any of the following serious side effects, tell your doctor immediately and stop taking the medicine:

Frequency not known (cannot be estimated from available data):

- Hypersensitivity reaction, (allergy like reactions such as itching, difficulties to breath)
- Swelling of deeper layers of skin (angioedema)
- Swelling in mouth and tongue (oedema)

Other side effects that might occur are listed below.

Common (may affect up to 1 in 10 people):

- Headache
- Sleepiness

Uncommon (may affect up to 1 in 100 people):

- Irritation, nervousness, restlessness,
- Sleeplessness (insomnia), abnormal dreams, nightmares, night sweats, anxiety, anxious restlessness, physical weakness, lack of energy and enthusiasm
- Migraine
- Dizziness
- High blood pressure
- Mouth ulceration
- Dry mouth
- Nausea, abdominal pain, gastric disorder
- Skin disorders (dermatitis, pruritus, rash, dry skin)
- Pain in arms and legs
- Menopausal symptoms
- Chest pain

- Excretion of glucose in the urine, excess proteins in the urine
- Changes in the composition of your blood which can cause yellowing of the skin and eyes
- Abnormal liver function tests
- Increased weight

Rare (may affect up to 1 in 1,000 people):

- Shingles (herpes zoster)
- Reduced number of white blood cells in the blood
- Reduced number of blood platelets
- Low calcium or sodium levels in the blood
- High level of blood fats
- Changes in mood, aggression, agitation, crying, stress symptoms, feeling confused (disorientation), early morning awakening, increased sex drive (increased libido), depressed mood, depression
- Fainting, memory impairment, disturbance in attention, dreamy state, uncomfortable sensation in legs (restless legs syndrome), poor quality sleep, tiredness (fatigue)
- Visual impairment, blurred vision, increased tearing
- A feeling of dizziness or spinning (vertigo), dizziness when standing or sitting
- Faster heartbeats, chest pain due to angina pectoris
- Acid reflux, gastrointestinal disorder, blistering in the mouth, tongue ulceration, stomach upset, vomiting, abnormal bowel sounds, increased salivation, bad breath, flatulence, abdominal discomfort, inflammation of the stomach lining
- Abnormal dermal sensation, skin disorders (eczema, erythema, psoriasis, rash), nail disorder, sudden feeling of heat (hot flush)
- Pain, arthritis, muscle spasms, neck pain, night cramps
- Passing large volumes of urine, presence of red blood cells in the urine, need to urinate at night
- Prolonged erection (priapism)
- Inflammation or swelling of prostate gland
- Thirst
- Increased liver enzymes, abnormal blood electrolytes and abnormal laboratory tests
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Frequency not known (cannot be established from the available data, reported after use by adults):

- High blood glucose level
- Spontaneous flow of milk from the chest

Additional side effects in children and adolescents

A low frequency of generally mild side effects has been reported. The most common side effects were:

- Headache
- Hyperactivity
- A feeling of dizziness or “spinning” (vertigo)
- Abdominal pain

No serious side effects have been observed.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#).* By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Melatonin Evolan

Keep this medicine out of the sight and reach of children.

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

After first opening: Store below 25°C. Use within 3 months.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

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.

6. Contents of the pack and other information

What Melatonin Evolan contains

- The active substance melatonin. 1 ml of oral solution contains 1 mg melatonin.
- The other ingredients are water, sucralose (E955), benzyl alcohol, sodium ascorbate, propylene glycol (E1520), strawberry flavour.

What Melatonin Evolan looks like and contents of the pack

A clear, pale yellow to yellow coloured oral solution with strawberry taste.

Brown glass bottle with plastic screw cap. A 5 ml plastic dosing spoon, graduated 1-2-3-4-5 ml, is provided.

Package sizes: 100 ml, 150 ml and 200 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This leaflet was last revised in

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