

Package leaflet: Information for the user

Melatonin 1mg/ml oral solution

melatonin

Read all of this leaflet carefully before you or your child 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.

The name of your medicine is Melatonin 1mg/ml oral solution, it will be referred to as Melatonin oral solution for ease hereafter.

What is in this leaflet

1. What Melatonin oral solution is and what it is used for
2. What you need to know before you use Melatonin oral solution
3. How to use Melatonin oral solution
4. Possible side effects
5. How to store Melatonin oral solution
6. Contents of the pack and other information

1. What Melatonin oral solution is and what it is used for

Melatonin oral solution contains the active substance melatonin, which is a hormone produced naturally by the body. This hormone helps regulate the body's day- and night rhythm. Melatonin oral solution can be used for treatment of jet-lag in adults and sleep onset insomnia in children and adolescents aged 6-17 years with attention-deficit hyperactivity disorder (ADHD) where other sleep routine measures have not been sufficient. Jet-lag refers to the symptoms caused by the time difference when travelling across several time zones.

2. What you need to know before you use Melatonin oral solution

Do not take Melatonin oral solution

- 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 oral solution.

- if you have epilepsy. Melatonin may increase seizure frequency in patients with epilepsy
- if you have an autoimmune disease (where the body is 'attacked' by its own immune system)
- if you have diabetes or impaired glucose tolerance, as this medicine may increase the level of glucose in your blood
- if you suffer from significantly impaired liver function or kidney function
- if you smoke. Smoking may reduce the effect of Melatonin oral solution as components of tobacco smoke can increase the breakdown of melatonin by the liver.

“Note: Make sure you receive the same melatonin medicine when you collect your prescription unless your doctor has agreed to change to a different melatonin medicine”.

Children and adolescents

Do not give this medicine to children below 6 years as its safety and efficacy are unknown.

Other medicines and Melatonin oral solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Fluvoxamine (used for the treatment of depression and obsessive-compulsive disorder)
- Psoralens (used for the treatment of skin disorders e.g. psoriasis)
- Cimetidine (used for the treatment of stomach problems such as ulcers)
- Estrogens (used in contraceptives or hormone replacement preparations)
- Quinolones (used in the treatment of bacterial infections)
- Rifampicin (used in the treatment of bacterial infections)
- Carbamazepine (used in the treatment of epilepsy)
- Benzodiazepines and non-benzodiazepine hypnotics (medicines used to induce sleep, e.g. midazolam, temazepam, and zaleplon, zolpidem, zopiclone)
- Warfarin (anticoagulants).

Melatonin oral solution with food, drink and alcohol

- This medicine should not be taken with food (see Section 3).
- As alcohol can impair sleep and potentially worsen certain symptoms of jet-lag (e.g. headache, morning fatigue, concentration) it is recommended that alcohol is not consumed while taking this medicine.

Pregnancy, breast-feeding and fertility

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

Pregnancy

Melatonin oral solution is not recommended if you are pregnant. Melatonin crosses the placenta and there is insufficient information on the risk this may pose to the unborn child. If you are woman of childbearing potential you have to use contraception.

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.

Fertility

Melatonin oral solution is not recommended in women and men planning to have a baby as there is insufficient information on the effects of melatonin on female and male fertility.

Driving and using machines

Melatonin oral solution 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 oral solution contains sorbitol and propylene glycol.

This medicine contains 140 mg sorbitol and 150.50 mg propylene glycol in each ml.

Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine.

3. How to use Melatonin oral solution

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 jetlag:

The recommended dose for adults and elderly is 3 mg (3 ml) daily for a maximum of 5 days. When the effect of Melatonin oral solution is inadequate, 6 mg (6 ml) can be taken.

The first dose should be taken on arrival at destination at your usual bed-time. Intake on the following days should also be at your usual bed-time. The oral solution should not be taken before 20:00 hours or after 04:00 hours.

Food should not be consumed 2 hours before or 2 hours after intake of Melatonin oral solution.

Melatonin oral solution may be taken for a maximum of 16 treatment periods per year.

Sleep onset insomnia in children and adolescents aged 6-17 years old with ADHD:

The recommended starting dose is 1-2 mg (1-2 ml) before bedtime. If there is no improvement in your or your child's symptoms your doctor may increase the dose of Melatonin oral solution, to find the most suitable dose for you or your child. The maximum daily dose that you or your child will receive is 5 mg.

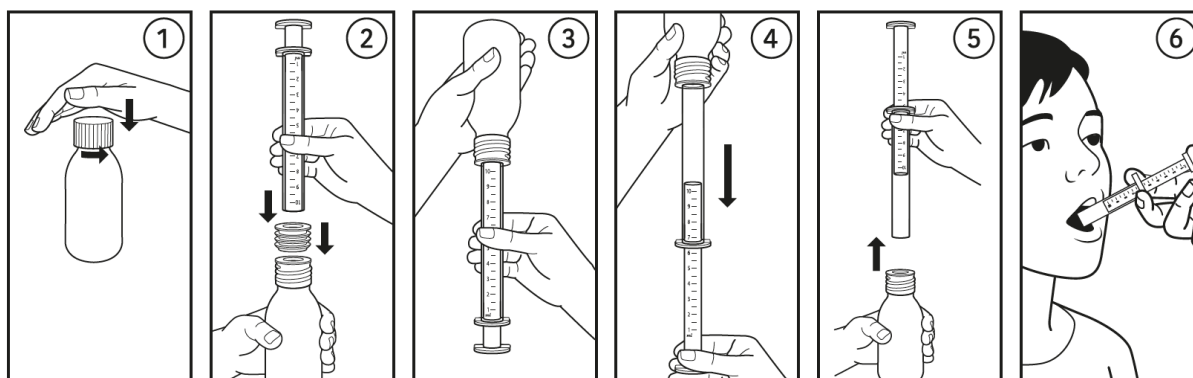
Treatment should be followed up regularly by a doctor (at least every 6 months is recommended) to see if it is still appropriate. Treatment should be interrupted once a year to see if treatment is still needed.

Method of administration

Melatonin oral solution is for oral use only.

A 10 ml graduated oral syringe with intermediate graduations of 0.5 ml and a "Press-In" Bottle Adapter (PIBA) are provided with the product.

1. Open the bottle and at first use insert the "Press-In" Bottle Adapter (PIBA) into the bottle neck, and insert syringe into PIBA (see pictures 1-2).
2. With syringe in place, invert the bottle and draw out the required volume (see pictures 3-4).
3. Return the bottle to the upright position and remove the filled syringe (see picture 5).
4. Discharge the syringe contents into the mouth (see picture 6)
5. Rinse the syringe and replace the cap on the bottle (PIBA remains in place).



If you take more Melatonin oral solution than you should

If you or your child have taken more Melatonin oral solution than recommended and you do not feel well, please contact your doctor, hospital or pharmacy.

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

If you forget to take Melatonin oral solution

If you forget to take your dose at bedtime and wake during the night you may take the forgotten dose but at no later than 04:00 hours.

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

If you stop taking Melatonin oral solution

If you stop taking Melatonin oral solution, it will not have any harmful effects or withdrawal symptoms.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

If you or your child experience any of the following serious side effects stop taking this medicine and contact your doctor *immediately*:

Frequency Not known:

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

Other side effects that might occur are listed below.

Common side effects (may affect up to 1 in 10 people)

- Headache
- Sleepiness

Uncommon side effects (may affect up to 1 in 100 people)

- Irritability, nervousness, restlessness
- Abnormal dreams, night sweats, anxiety, lack of energy and enthusiasm
- Migraine
- Dizziness
- High blood pressure
- Abdominal pain, mouth ulcers, dry mouth, nausea
- Skin disorders (dermatitis, pruritus, rash, dry skin)
- Pain in arms and legs
- Menopausal symptoms
- Chest pain
- Excretion of glucose in the urine, excess protein in the urine
- Abnormal liver function tests
- Increased weight

Rare side effects (may affect up to 1 in 1000 people)

- Shingles (herpes zoster)
- Reduced number of white blood cells in the blood
- Reduced number of blood platelets
- High levels of blood fats
- Changes in mood, aggression, agitation, crying, stress symptoms, feeling confused (disorientation), increased sex drive (increased libido), depressed mood, depression
- Fainting, memory impairment, disturbance in attention, uncomfortable sensation in legs (restless legs syndrome), poor quality sleep, tiredness (fatigue)
- Visual impairment, blurred vision, increase tearing
- A feeling of dizziness or spinning (vertigo), dizziness when standing or sitting
- Faster heartbeats, angina pectoris
- Acid reflux, gastrointestinal disorder, blistering in the mouth, tongue ulceration, stomach upset, vomiting, abnormal bowel sounds, increased salivation, bad breath, wind, abdominal discomfort, inflammation of the stomach lining
- Abnormal skin sensations (paresthesia), skin disorders (eczema, erythema, psoriasis), 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), swelling of the prostate (prostatitis)
- Thirst
- Increased liver enzymes, abnormal blood electrolytes, abnormal laboratory tests

Not known (frequency cannot be estimated from available data)

- Spontaneous flow of milk from the breasts (also in men)
- High blood sugar

Additional side effects in children and adolescents

A low frequency of generally mild side effects has been reported. The most common adverse effects were headache, hyperactivity, a feeling of dizziness or “spinning” (vertigo) and abdominal pain. No serious adverse 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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Melatonin oral solution

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

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

Store in the original package in order to protect from light.

After first opening do not store above 25°C and use within 2 months.

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 oral solution contains

- Each 1 ml of Melatonin oral solution contains 1 mg of the active substance melatonin.
- The other ingredients are:
Propylene glycol (E1520), sorbitol liquid (non crystallising) (E420), sucralose (E955), strawberry flavour (including propylene glycol (E1520)), purified water, hydrochloric acid, concentrated (E507).

What Melatonin oral solution looks like and contents of the pack

Melatonin oral solution is a clear, colourless to yellowish solution with characteristic strawberry odour. It is supplied in a 60 ml or 150 ml, amber, type III glass bottle safely closed with an HDPE child-resistant, tamper-evident screw cap with an LDPE liner. An LDPE, CE marked 10 ml graduated oral syringe with intermediate graduations of 0.5 ml and an LDPE, CE marked “press-in” syringe/bottle adaptor are also provided.

Not all pack sizes may be marketed.

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