

Package leaflet: Information for the user

Melatonin 1mg/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.

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. Melatonin oral solution can be used for treatment of jet-lag in adults. Jet-lag can be recognized by sleep disturbances, daytime tiredness, fatigue, mild mental impairment, irritability and digestive system disturbances experienced after flying.

How Melatonin oral solution works

Melatonin is a hormone produced by the body that synchronizes the body's biological day-and-night rhythm. The biological rhythm can be disturbed by travelling across time zones. This is known as jet-lag. The symptoms and their severity vary between individuals, but are generally worse and last longer the more time zones are crossed. Melatonin oral solution can help restore the normal day-and-night rhythm and reduce the symptoms.

You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

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.

Children and adolescents

Do not give this medicine to children and adolescents between 0 and 18 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), as fluvoxamine may increase the effect of melatonin
- Psoralens (used for the treatment of skin disorders e.g. psoriasis), as psoralens may increase the effect of melatonin
- Cimetidine (used for the treatment of stomach problems such as ulcers), as cimetidine may increase the effect of melatonin
- Estrogens (used in contraceptives or hormone replacement preparations), as estrogens may increase the effect of melatonin
- Quinolones (used in the treatment of bacterial infections), as quinolones may increase the effect of melatonin
- Rifampicin (used in the treatment of bacterial infections), as rifampicin may decrease the effect of melatonin
- Carbamazepine (used in the treatment of epilepsy), as carbamazepine may decrease the effect of melatonin
- Benzodiazepines and non-benzodiazepine hypnotics (medicines used to induce sleep, e.g. midazolam, temazepam, and zaleplon, zolpidem, zopiclone), as melatonin may enhance the sedative effect of such drugs, and may enhance certain side effects of zolpidem (morning sleepiness, nausea, confusion)
- Warfarin (anticoagulants), as melatonin may influence the effect of the anticoagulant warfarin.

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.

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 hr or after 04:00 hr.

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.

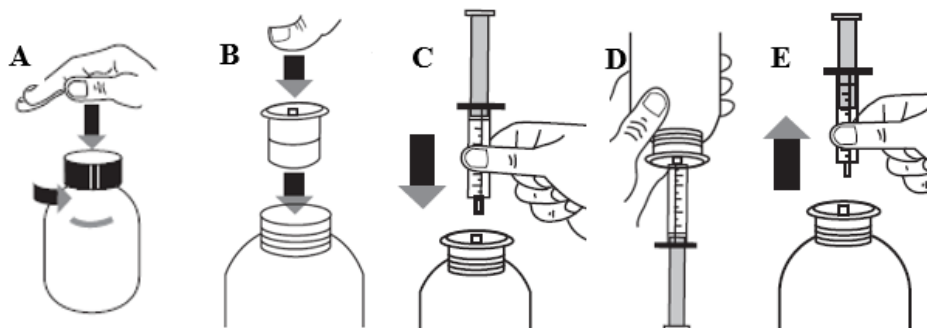
Method of administration

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) (see pictures A-B).

2. Insert the syringe into the PIBA and draw out the required volume from the inverted bottle (see pictures C-D).
3. Remove the filled syringe from the bottle in the upright position (see picture E).
4. Discharge the syringe contents into the mouth.
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 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 hr.

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

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

- Chest pain

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

- Reduced number of white blood cells in the blood
- Reduced number blood platelets, which increases the risk of bleeding or bruising
- Disorientation
- Fainting
- Visual impairment, including blurred vision

- Feeling your heartbeat ('pounding chest')
- Blood (red blood cells) in the urine
-

Not known (frequency cannot be estimated from available data)

- Severe allergic reaction resulting in swelling of the tongue or lining of the mouth

Non-serious side effects

If you experience any of the following non-serious side effects contact your doctor or pharmacist:

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

- Headache
- Drowsiness

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

- Irritability, nervousness, restlessness, abnormal dreams, anxiety
- Dizziness
- High blood pressure
- Abdominal pain, upper abdominal pain, indigestion, mouth ulceration, dry mouth, nausea
- Itching, rash, dry skin
- Excretion of glucose in the urine, excess protein in the urine
- Feeling unwell
- Weight increase

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

- High levels of certain fat molecules (triglycerides) in the blood
- Altered mood, aggression, increased sex drive
- Memory impairment, restless legs syndrome, 'pins and needles' sensation
- Watery eyes
- Hot flushes
- Vomiting, wind, excess saliva, bad breath, inflammation of the stomach lining
- Nail disorder
- Arthritis, muscle spasms
- Passing large volumes of urine
- Prolonged erection that might be painful, inflammation of the prostate gland
- Thirst
- Abnormal levels of electrolytes in the blood

Not known (frequency cannot be estimated from available data)

- Hypersensitivity reactions
- High blood glucose level
- Flow of milk from the breasts (also in men)

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.

Marketing Authorisation Holder

Colonis Pharma Ltd.
25 Bedford Square,
Bloomsbury,
London,
WC1B 3HH,
United Kingdom.

Manufacturer

RAFARM SA
Thesi Pousi-Xatzi Agiou Louka,
Paiania Attiki,
19002, PO Box 37,
Greece.

This leaflet was last revised in August 2021.