

Package leaflet: Information for the user
Melatonin 2mg/ml Oral Solution

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 2mg/ml Oral Solution but it will be referred to as 'Melatonin' throughout this leaflet.

What is in this leaflet

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

1. What Melatonin is and what it is used for

Melatonin 2mg/ml Oral Solution contains the active substance melatonin. Melatonin 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 work

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 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 take Melatonin

Do not take Melatonin

- ▶ 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

- ▶ 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 as components of tobacco smoke can increase the breakdown of melatonin by the liver.

Care should be exercised when changing between different formulations/ products, as changing formulations may increase the risk of drowsiness.

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

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 disorder 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
- ▶ Oestrogens (used in contraceptives or hormone replacement preparations), as oestrogens 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 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 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 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 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 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 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 contains

Propylene glycol (E1520): This medicinal product contains 174.25mg propylene glycol in each 5ml which is equivalent to 34.85mg/ml.

3. How to use Melatonin

Always use 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 1.5ml (3mg) daily for a maximum of 5 days. When the effect of Melatonin is inadequate, 3ml (6mg) 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 medicine should not be taken before 20:00 hr or after 04:00 hr.

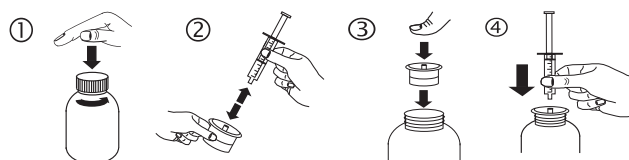
Melatonin may be taken for a maximum of 16 treatment periods per year.

Method of administration

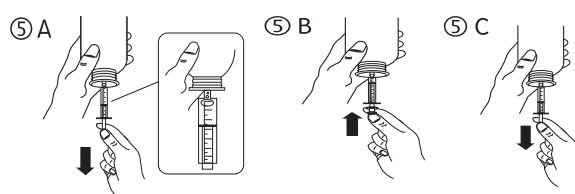
Swallow the solution with water or other liquid (e.g. milk, fruit juice). Food should not be consumed 2 hours before or 2 hours after intake of Melatonin.

Instructions for the use of syringe:

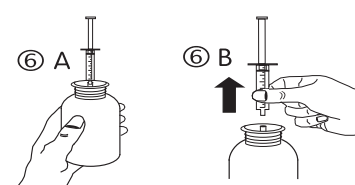
- Open the bottle: press the cap and turn it anticlockwise (figure 1).
- Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



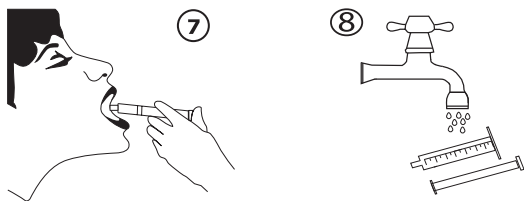
- Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).



- Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



- e) Empty the contents of the syringe into the patient's mouth by pushing the piston to the bottom of the syringe (figure 7). The contents of the syringe should be emptied into the side cheek of the patient's mouth to avoid a choking hazard. Close the bottle with the plastic screw cap. Wash the syringe with water (figure 8).



If you take more Melatonin than you should

If you have taken more Melatonin 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

If you forget to take a solution 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

If you stop taking Melatonin, it will not have 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.

Serious side effects

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

Uncommon: may affect up to 1 in 100 people

- ▶ Chest pain

Rare: may affect up to 1 in 1,000 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: may affect up to 1 in 10 people

- ▶ Headache
- ▶ Drowsiness

Uncommon: 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: may affect up to 1 in 1,000 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

- ▶ 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 bottle label after 'EXP'. The expiry date refers to the last day of that month.
- ▶ This medicinal product does not require any special storage conditions.
- ▶ Discard 30 days after first opening.
- ▶ Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- ▶ 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 contains

The active substance is melatonin.

Each ml of oral solution contains 2mg melatonin.

The other ingredients are propylene glycol (E1520), glycerol (E422) and orange flavour (containing propylene glycol (E1520)).

What Melatonin looks like and contents of the pack

Melatonin is a clear, colourless to pale yellow colour solution supplied in amber glass bottle with tamper evident, child resistant plastic cap. The pack also contains a 5ml oral syringe with 0.1ml graduation for measuring the dose and a syringe adaptor.

Melatonin is supplied in bottles containing 25ml solution.

Marketing Authorisation Holder and Manufacturer:

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Ruislip, Middlesex
HA4 0NU, UK

If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.

This leaflet was last revised in 04/2024.