

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 or your child 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 Oral Solution is and what it is used for
2. What you need to know before you take Melatonin Oral Solution
3. How to take 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

This medicine contains the active substance melatonin. Melatonin is a hormone produced by the body that synchronizes the body's biological day and night rhythm.

Melatonin Oral Solution is used for:

- Treatment of delayed sleep wake up phase disorder (DSWPD) (disruption of the body's day and night rhythm) in children and adolescents (6 to 17 years old) and adults up to 25 years of age, where healthy sleeping routines have not worked well enough.
- Short-term treatment of jet lag in adults. Jet lag refers to the symptoms caused by the time difference when travelling through several time zones.
- Insomnia (sleeplessness) in children and adolescents (6 to 17 years old) with ADHD, where healthy sleeping routines have not worked well enough.
- Sedation of children and adolescents (1 to 18 years old) who are having diagnostic procedures such as electroencephalograms (EEG), auditory brain response (ABR) testing and Magnetic Resonance Imaging (MRI) in hospital.

2. What you need to know before you take Melatonin Oral Solution

Do not take Melatonin Oral Solution if

- you are allergic to melatonin or any of the 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.

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.
- 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, 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 (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. Effective contraception must be used by women of childbearing potential.

Breast-feeding

Melatonin Oral Solution is not recommended if you are breast-feeding. Melatonin is excreted in human milk, and a risk to the 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 use. Therefore, this medicine should not be taken prior to driving or using machines.

Melatonin Oral Solution contains methyl parahydroxybenzoate (E218)

This may cause an allergic reaction. This allergy may be a delayed reaction.

3. How to take 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.

Short-term treatment of jet lag (sleep disorder after a long flight)

The recommended dose is:

3mg (3ml) daily for a maximum of 5 days. The dose may be increased to 6mg (6ml) if the standard dose does not adequately alleviate symptoms. The dose that adequately alleviates symptoms should be taken for the shortest period needed, up to a maximum of 5 days.

The first dose should be taken on arrival at the destination at your usual bed-time. The next dose on the following day should also be at your usual bed-time. Melatonin Oral Solution should not be taken before 20:00hr or after 04:00hr, at the destination.

Food should not be consumed 2 hours before or 2 hours after taking Melatonin Oral Solution.

Melatonin Oral Solution may be taken for jet lag, for a maximum of 16 treatment periods per year.

Delayed sleep wake phase disorder

The recommended dose is:

1 to 5mg (1 to 5ml) per day, 1 to 2 hours before going to bed. The maximum daily dose is 5mg (5ml). Your doctor will likely start you at a low dose (1 to 2mg) and adjust it depending on your response.

Insomnia (sleeplessness) in children and adolescents with ADHD

In children and adolescents with ADHD, the recommended starting dose is 1 to 2mg (1 to 2 ml), 30 to 60 minutes before bedtime. The dose can be increased up to a maximum of 5mg (5ml) per day depending on your response.

For both insomnia and DSWPD, you or your child should be monitored by your doctor at regular intervals (recommended at least every 6 months) to check that Melatonin Oral Solution is still the right treatment for you/them. Treatment should be interrupted once a year to see if it is still needed. For some patients, treatment can be continued past the usual age ranges if the doctor considers it appropriate.

Sedation

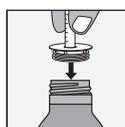
Melatonin Oral Solution will be given 30 to 45 minutes before the start of the procedure. The dose will be determined by your doctor depending on your child's weight. A 'top-up' dose may be given if sleep is not achieved 45 minutes after the first dose - this will usually be half the first dose. Only one melatonin assisted EEG should be performed per 24 hour period.

Contents of the box

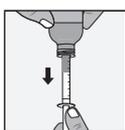
The box containing this medicine contains a bottle adaptor and a 10ml dosing syringe with 0.5 millilitre (ml) increments. Each 1ml increment is equivalent to 1mg of Melatonin Oral Solution. Instructions are provided below for using the adaptor and dosing syringe. If you have any questions about the dose or how to use the adaptor and syringe, you should ask your pharmacist.

Instructions for using the dosing syringe:

1. Open the bottle and at first use, insert the "Press-In" Bottle Adaptor (PIBA) with the syringe in place.



2. Invert the bottle (with the syringe attached) and fill the syringe with the liquid by pulling the syringe plunger down to just beyond the graduation mark corresponding to the quantity in millilitres (ml). Remove air bubbles from the syringe by pushing the plunger up to the appropriate graduation mark.



3. Return the bottle to an upright position with the syringe still in the PIBA/bottle. Remove the syringe from the bottle.



4. Discharge the syringe contents into the mouth.



5. Repeat steps 2-4 if doses greater than 5ml are required.

6. 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 forgotten dose. Take your next dose at the correct time.

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 of 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 (e.g sodium, potassium, calcium)

Not known

(frequency cannot be estimated from available data)

- Hypersensitivity reactions, (allergy like reactions such as difficulty breathing, itching)
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the 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.

Do not store above 25°C. After opening 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

- The active substance is melatonin. Each 1ml of Melatonin Oral Solution contains 1mg of the active substance melatonin.
- The other ingredients are methyl parahydroxybenzoate (E218), potassium sorbate (E202), hydrochloric acid (E507), glycerol (E422) and purified water.

What Melatonin Oral Solution looks like and contents of the pack

Melatonin Oral Solution is a clear, colourless to slightly yellow solution.

It is supplied in a 150ml, amber, type III glass bottle safely closed with a high-density polyethylene (HDPE) child-resistant closure and tamper-evident screw cap. A low-density polyethylene (LDPE), CE marked 10ml graduated oral syringe with intermediate graduations of 0.5ml, and an LDPE CE marked "press in" syringe/bottle adaptor are also provided.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Aspire Pharma Ltd.
Unit 4, Rotherbrook Court
Bedford Road
Petersfield
Hampshire, GU32 3QG
United Kingdom

Manufacturer:

Yasenka d.o.o.
Dvanaest redarstvenika 2/c
Vukovar
32000
Republic of Croatia

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Aspire Pharma Limited	
Product name	Melatonin O/S
Size:	150ml
PL/PA no:	PL 35533/0179
Type:	Leaflet
Artwork dimensions (mm):	148x420mm
Reason for request:	Text update
Version no:	3.3
Date of revision:	21.3.24
Font(s):	Helvetica Neue LT 9pt
A/W software:	Indesign CC



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