

Package leaflet: Information for the user

Melatonin Aspire 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.

What is in this leaflet:

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

1. What this medicine 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.

<invented name> is used for:

- 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.
- Sleep onset insomnia in children and adolescents (6 to 17 years old) with ADHD, where other healthy sleeping routines have not worked well enough.

2. What you need to know before you take this medicine

Do not take this medicine 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 this medicine:

- 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 have impaired liver or kidney function.
- if you smoke. Smoking may reduce the effect of this medicine as components of tobacco smoke can increase the breakdown of melatonin by the liver.

If you are a woman of childbearing potential. Contraceptives should be used during treatment with melatonin. This medicinal product may however be affected by certain contraceptives, see the section 'Other medicines and melatonin' for more information.

Children and adolescents

Do not give this medicine to children or adolescents under 18 years for the indication jet-lag as its safety and efficacy are unknown for this indication.

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

Other medicines and <invented name>

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.
- Smoking may decrease the effect of melatonin.
- Carbamazepine or phenytoin (medicines used in the treatment of epilepsy), as these medicines may decrease the effect of melatonin.
- Beta-blockers (used to treat high blood pressure), as these medicines may reduce the effects of melatonin.
- Nifedipine (used to treat high blood pressure), as melatonin may reduce the effect of nifedipine.
- 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.
- NSAID medicines such as acetylsalicylic acid and ibuprofen.
- Caffeine, as melatonin interacts with caffeine.

<invented name> with food, drink and alcohol

Do not drink alcohol before, during or after taking this medicine, because of enhanced drowsiness when alcohol is taken with melatonin.

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.

Contraceptives for fertile women and young girls

Fertile women and young girls should use contraceptives when taking melatonin. Because some contraceptives may increase melatonin levels in the body, the choice of contraceptive should be discussed with a doctor see section 'Other medicines and melatonin'.

Pregnancy

This medicine 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.

Breast-feeding

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

Fertility

This medicine 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

This medicine 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.

This medicine contains methyl parahydroxybenzoate (E218)

This may cause an allergic reaction (possibly delayed).

3. How to take this medicine

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 in adults

The recommended dose is 1 to 5 mL (equivalent to 1 to 5 mg) daily for a maximum of 5 days.

Maximum recommended dose: 5 mL (equivalent to 5 mg) per day, for 5 days.

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.

This medicine should not be taken before 20:00hr or after 04:00hr at the destination.

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

The recommended starting dose is 1 to 2 mL (1 to 2 mg), 30 to 60 minutes before bedtime.

The dose will be adjusted individually to a maximum of 5 mL (5 mg) daily, regardless of age. The lowest dose possible will be given.

Treatment should be followed up regularly by a doctor to see if it is still appropriate.

How to use the oral syringe

1. Open the bottle and at first use, insert the “Press-In” Bottle Adapter (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 dose in 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 slowly into the mouth and swallow the medicine.
5. Rinse the syringe and replace the cap on the bottle (PIBA remains in the bottle).

If you take more <invented name> than you should

If you or your child has accidentally taken too much medicine, or if for example a child has ingested the medicine by mistake, contact a doctor or pharmacist as soon as possible
The most common symptoms of overdose are drowsiness, headache, dizziness, and nausea.

If you forget to take <invented name>

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.

If you stop taking <invented name>

If you stop taking this medicine, 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 or go to the emergency department if you experience the following:

- Allergy like reactions such as difficulty breathing and itching (hypersensitivity reaction)
- Angioedema, with symptoms such as swelling of the face, tongue or throat; difficulty swallowing; hives and breathing difficulties
- Swelling in the mouth and tongue (oedema)

The frequency of these side effects is not known (cannot be estimated from available data).

Other side effects

If you experience any of the following side effects, contact your doctor or pharmacist:

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

- Headache
- Tiredness

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

- Irritability, nervousness, restlessness, insomnia, abnormal dreams, nightmares, anxiety
- Migraine, lethargy, psychomotor hyperactivity, dizziness
- High blood pressure
- Abdominal pain, upper abdominal pain, indigestion, mouth ulceration, dry mouth, nausea
- Changes in the composition of your blood which can cause yellowing of the skin and eyes (hyperbilirubinaemia)
- Dermatitis, night sweats, itching, rash, dry skin
- Pain in arms and legs
- Excretion of glucose in the urine, excess protein in the urine
- Symptoms of menopause
- Chest pain, lack of energy (asthenia)
- Feeling unwell
- Abnormalities detected in liver function test
- Weight increase

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

- Reduced number of white blood cells in the blood (leukopenia)
- Reduced number blood platelets, which increases the risk of bleeding or bruising (thrombocytopenia)
- High levels of certain fat molecules (triglycerides) in the blood

- Altered mood, aggression, agitation, crying, stress symptoms, feeling confused (disorientation), waking early, experiencing depressed mood, increased sex drive
- Fainting, memory impairment, disturbed attention, dreamy state, poor quality sleep, uncomfortable sensation in legs (restless legs syndrome), 'pins and needles' sensation
- Visual impairment, including blurred vision, watery eyes
- A feeling of spinning (vertigo), dizziness when standing or sitting
- Feeling your heartbeat (pounding chest), chest pain due to angina pectoris
- Hot flushes
- Acid reflux, gastrointestinal disorder, blistering in the mouth, tongue ulceration, stomach upset, vomiting, abnormal bowel sounds, wind, excess saliva, bad breath, abdominal discomfort, inflammation of the stomach lining
- Abnormal skin sensation (paresthesia), skin disorders (eczema, erythema, psoriasis), nail disorder
- Arthritis, muscle spasms, neck pain, night cramps
- Passing large volumes of urine, blood (red blood cells) in the urine, need to urinate at night
- Prolonged erection that might be painful, inflammation of the prostate gland
- Fatigue, pain, thirst
- Abnormal levels of electrolytes in the blood (e.g. sodium, potassium, calcium)

Not known (frequency cannot be estimated from available data)

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- High blood glucose level
- Drowsiness, sedation
- 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 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 this medicine

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.

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 this medicine contains

- The active substance is melatonin. Each 1mL of this medicine contains 1 mg of melatonin.
- The other ingredients are methyl parahydroxybenzoate (E218), potassium sorbate (E202), hydrochloric acid (E507 (for pH adjustment)), glycerol (E422) and purified water.

What this medicine looks like and contents of the pack

This medicine is presented as 150 mL clear, colourless to slightly yellow oral solution in an amber, type III glass bottle with a plastic child-resistant closure screw cap. A plastic 10 mL graduated oral syringe with intermediate graduations of 0.5 mL, and a plastic "press in" syringe/bottle adaptor are also included in the carton.

Marketing Authorisation Holder and Manufacturer

<to be completed nationally>

This leaflet was last revised in 2025-03-21