Package leaflet: Information for the user

Melatonin Glenmark 1 mg/ml oral solution
melatonin

Read all of this leaflet carefully before you start using 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 described 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 [product name] is and what it is used for

[product name] 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.

[product name] is used for:
- short-term treatment of jet-lag, in adults only. Jet-lag refers to the symptoms caused by the time difference when travelling across several time zones.
- sleep onset insomnia in children and adolescents aged 6-17 years with attention deficit hyperactivity disorder (ADHD), where other healthy sleeping routine measures have not worked well enough.

2. What you need to know before you take [product name]

Do not take [product name]
- 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 [product name].
- if you have epilepsy, as melatonin may increase or decrease seizure frequency.
- 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 function or kidney function.
- if you smoke. Smoking may reduce the effect of [product name], 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 [product name]. This medicinal product may however be affected by certain contraceptives, see the section 'Other medicines and [Product name]' 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 as its safety and efficacy are unknown.

Other medicines and [product 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 (used in the treatment of epilepsy), as carbamazepine 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, and zaleplon, zolpidem, zopiclone), as melatonin may enhance the sedative effect of such drugs, and it may enhance certain side effects of zolpidem (morning sleepiness, nausea, confusion).
- Anticoagulants, as melatonin may influence the effect of the anticoagulants.
- Thioridazine/Imipramine, as melatonin may enhance the feelings of drowsiness and inability to perform tasks
- NSAID medicines such as acetylsalicylic acid and ibuprofen.
- Caffeine, as melatonin interacts with caffeine.

[product name] with alcohol
Do not drink alcohol before, during or after taking (product name), 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.

<u>Contraceptives for fertile women and young girls</u>
Fertile women and young girls should use contraceptives when taking (product name). Because some contraceptives may increase melatonin levels in the body, the choice of contraceptive should be discussed with a doctor (see “Other medicines and (product name)”).

<u>Pregnancy</u>
[product name] 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
[product name] is not recommended if you are breast-feeding. Melatonin is excreted in human milk, and a risk to the breastfed baby cannot be excluded.

Driving and using machines
This medicine 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.

[product name] contains sodium methyl parahydroxybenzoate
May cause allergic reactions (possibly delayed).

[product name] contains propylene glycol
This medicine contains 150 mg propylene glycol in each ml.

[product name] contains sorbitol
This medicine contains 140 mg sorbitol in each ml.
Sorbitol is a source of fructose. If your doctor has told you that you (or your child) 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 (or your child) take or receive this medicine.

[product name] contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

3. How to take [product name]

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults with jet-lag:
The recommended dose is 0.5-5 ml (equivalent to 0.5 to 5 mg) for a maximum of 5 days.
Maximum dose: 5 ml (equivalent to 5 mg) per day, for 5 days.
The first dose should be taken on arrival at destination at your usual bedtime. Intake on the following days should also be at your usual bedtime.
The oral solution should not be taken before 20:00 or after 04:00.

Sleep onset insomnia in children and adolescents aged 6-17 years old with ADHD:
The recommended starting dose is 1-2 ml (1-2 mg) 30-60 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.
The maximum daily dose that you or your child will receive is 5 mg.

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

Diabetes
If you have or your child has diabetes or impaired glucose tolerance, food should not be consumed 2 hours before or 2 hours after intake of <Invented name>, see Warnings and precautions.

How to give <invented name>

[product name] should be swallowed

Use the oral syringe provided to deliver your specific dose.

How to measure the correct dose:
Use the bottle adapter and syringe included in the carton.

1) Make sure the cap is firmly closed before you shake the bottle.
2) Open the cap by pressing down and turn anti-clockwise.
3) At first use, insert the adaptor into the neck of the bottle, by keeping the bottle on a flat surface and the adaptor's flat surface facing up and pressing it down. The adaptor must after this always be kept in the bottle.
4) Make sure the plunger is fully down in the syringe before your insert the syringe into the adaptor.
5) Invert the bottle upside down and slowly pull the plunger down fully so that the syringe fills with medicine. Push the plunger back up completely to expel any large air bubbles that may be trapped inside the oral syringe. Then pull the plunger slowly back to the volume you need for your dose.
6) Turn the whole bottle with the syringe still included the right way up before you take the syringe out of the bottle.
7) Sit upright and discharge the syringe content slowly into the mouth and swallow the medicine.
8) Rinse the syringe and replace the cap on the bottle (the adaptor remains in the bottle).

If you take more [product 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 [product name]
If you forget to take your dose at bedtime and wake during the night you may take the forgotten dose but no later than 04:00 in the morning.

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

If you stop taking [product name]
If you stop taking [product name], 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 or your child experience any of the following serious side effects stop taking this medicine and contact your doctor immediately.

The frequency of these side effects is not known (cannot be estimated from the available data):
- Hypersensitivity reaction, (allergy like reactions such as difficulty to breathe, itching)
  Angioedema, with symptoms such as swelling of the face, tongue or throat; difficulty swallowing; hives and breathing difficulties
- Swelling in mouth and tongue (oedema)

Other side effects

In addition, the following side effects (listed by frequency) may occur.

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, physical weakness, lack of energy and enthusiasm
- Migraine
- Dizziness
- High blood pressure
- Abdominal pain, mouth ulcers, dry mouth, nausea
- Changes in the composition of your blood which can cause yellowing of the skin and eyes
- 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
- Low calcium or sodium levels in the blood
- High levels of blood fats
- Changes in mood, aggression, agitation, crying, stress symptoms, feeling confused (disorientation), early morning awakening, increased sex drive (increased libido), depressed mood, depression
- Fainting, memory impairment, disturbance in attention, dreamy state, 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)
- High blood sugar
- Drowsiness, sedation
- Spontaneous flow of milk from the breasts (also in men)

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, 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 [product name]

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 the bottle label after ‘EXP’. The expiry date refers to the last day of that month.

Store below 30°C.
Store in the original package in order to protect from light.

[product name] should not be used longer than 6 months after first opening.

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 [product name] contains
The active substance is melatonin.
The other ingredients are sodium methyl parahydroxybenzoate (E 219), sorbitol liquid (non-crystallising) (E 420), propylene glycol (E 1520), xanthan gum, citric acid, orange flavour, sodium citrate, saccharin sodium, purified water.

What [product name] looks like and contents of the pack

[product name] is a colourless to slightly yellowish, opalescent solution.

[product name] is packed in amber (type III) glass bottle of 100 ml or 150 ml oral solution, sealed with a child-proof and tamper evident plastic cap, with syringe adaptor and plastic syringe of 5 ml (with 0.1ml graduation).

Marketing Authorisation Holder

[to be completed nationally]

Manufacturer

[to be completed nationally]

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