

## **Package leaflet: Information for the user**

### **Melatonin EQL Pharma 1 mg/ml oral solution**

melatonin

**Read all of this leaflet carefully before you or your child 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 {Invented name} is and what it is used for
2. What you need to know before you or your child take {Invented name}
3. How to take {Invented name}
4. Possible side effects
5. How to store {Invented name}
6. Contents of the pack and other information

#### **1. What {Invented name} is and what it is used for**

{Invented name} contains the active substance melatonin, which is a hormone produced naturally by the body. The hormone helps regulate the body's day and night rhythm.

{Invented name} can be used for:

- Short-term treatment of jet lag in adults. Jet lag refers to symptoms, such as insomnia, caused by the time difference when traveling across several time zones.  
{Invented name} is recommended for adults flying over at least 5 time zones, especially eastern direction, and especially if they have experienced symptoms of jet lag during previous trips.
- Treatment of insomnia in children and adolescents (6 - 17 years) with attention deficit hyperactivity disorder (ADHD) where healthy sleeping routines have not worked well enough.

#### **2. What you need to know before you or your child take {Invented name}**

##### **Do not take {Invented 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 using {Invented name}, if you or your child:

- have diabetes or impaired glucose tolerance, as this medicine may increase the level of glucose in your blood.
- have liver problems, as {Invented name} is not recommended in patients with liver problems.
- have kidney problems, as caution should be exercised when {Invented name} is given to patients with kidney problems.
- have an autoimmune disease (where the body is "attacked" by its own immune system).

- have epilepsy, as melatonin might increase or decrease the frequency of seizures.
- are a fertile woman. Contraceptives should be used during treatment with {Invented name}. However, this medicine may be affected by some contraceptives, see the section "Other medicines and {Invented name} " for more information.

### **Children and adolescents**

Do not give this medicine to children under 18 years of age to treat jet lag as its safety and effects are unknown for this indication.

Insomnia: Do not give this medicine to children under 6 years of age since its safety and effects are unknown.

### **Other medicines and {Invented name}**

Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicines.

Taking {Invented name} at the same time as the following medicines may affect the way {Invented name} or the other medicines work:

- depression (e.g. fluvoxamine, citalopram)
- difficulty sleeping (e.g. zolpidem)
- epilepsy (carbamazepine, phenytoin)
- peptic ulcer (cimetidine, omeprazole, lansoprazole)
- skin diseases (psoralens),
- heart disease (verapamil)
- high blood pressure (nifedipine and other calcium channel blockers, beta-blockers)
- bacterial infections (ciprofloxacin, norfloxacin)
- tuberculosis (rifampicin)
- prevention and treatment of blood clots (warfarin)
- contraceptives containing estrogen and progestin
- hormone therapy due to menopausal symptoms
- pain and inflammation (nonsteroidal anti-inflammatory drugs, e.g. acetylsalicylic acid and ibuprofen)
- caffeine.

### **{Invented name} with smoking**

Smoking may reduce the effects of {Invented name}. Tell your doctor if you or your child smoke, start or stop smoking during treatment.

### **{Invented name} with alcohol**

Do not drink alcohol while taking {Invented name}, as this may reduce the effect of melatonin.

### **Pregnancy and breast-feeding**

If you or your child are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

#### *Contraceptives for fertile women and young girls*

Fertile women and young girls should use contraceptives while taking {Invented name}. Since some contraceptives can increase melatonin levels in the body, the choice of contraceptives should be discussed with a doctor (see "Other medicines and {Invented name} ").

#### *Pregnancy*

{Invented name} is not recommended if you are pregnant, or your child is pregnant. Melatonin crosses the placenta and there is insufficient information about the risk this may pose to the unborn child.

#### *Breast-feeding*

{Invented name} is not recommended if you or your child are breastfeeding. Melatonin is passed into breast milk and it cannot be excluded that there is a risk to the breastfed baby.

### **Driving and using machines**

{Invented name} can make you drowsy. If this happens, do not drive or use machines.

### **{Invented name} contains methylparaben**

This medicine contains methylparaben (methyl parahydroxybenzoate) which may cause allergic reactions (possibly delayed).

## **3. How to take {Invented 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 - 5 mg melatonin) daily, for a maximum of 5 days.

Recommended starting dose: 2 ml (equivalent to 2 mg melatonin).

Maximum recommended dose: 5 ml (equivalent to 5 mg melatonin) per day, for a maximum of 5 days.

Take the dose at the time of bedtime at the place of destination when travelling across at least 5 time zones, especially for trips in eastern direction. The oral solution should not be taken before 20:00 or after 04:00.

A maximum of 16 treatment cycles may occur per year.

### *Children and adolescents 6 - 17 years with ADHD with insomnia*

Recommended starting dose: 0.5 - 2 ml (corresponding to 0.5 - 2 mg melatonin) 30 - 60 minutes before bedtime.

The doctor may adjust the dose individually by small dose increases over time, to a maximum of 5 ml (5 mg melatonin) daily, regardless of age. The lowest possible dose should be used.

Treatment should be followed up regularly by a doctor (at least every 6 months is recommended) to see if it is still appropriate. Treatment should be interrupted once a year to see if treatment is still needed.

### How to take {Invented name}

{Invented name} should be swallowed.

### Instructions for use

1. Open the bottle by removing the bottle cap.
2. Insert the syringe into the bottle. Measure the dose prescribed by your doctor by slowly pulling out the plunger. Read the dose on the top edge of the plunger. Remove the syringe from the bottle.
3. You or the child should sit upright when taking/receiving {Invented name}. Aim the tip of the syringe at the inside of the cheek. Slowly push the plunger in and let the child swallow naturally. A quick feed of the medicine can cause discomfort.
4. Clean the inside of the syringe after each use.

### **Diabetes**

If you or your child have diabetes with impaired glucose tolerance, no food should be taken 2 hours before or 2 hours after taking {Invented name}, see "Warnings and precautions".

**If you take more {Invented name} than you should**

If you or your child have 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.

If you take more than the recommended daily dose, you or your child may feel drowsy, dizzy, nauseous and/or have a headache.

**If you forget to take {Invented name}**

If you or your child forget to take a dose and wake up during the night, you can take the missed 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 {Invented name}**

There are no known harmful effects if treatment is interrupted or stopped. The use of {Invented name} is not known to cause any withdrawal effects after treatment completion.

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.

If you or your child get any of these serious side effects, **stop taking the medicine immediately and see a doctor:**

Not known frequency cannot be estimated from the available data

- hypersensitivity reaction (allergy like reactions such as itching, difficulty to breathe)
- angioedema with symptoms such as swelling of the face, tongue, or throat; difficulty swallowing, hives and difficulty breathing.

Rare (may affect up to 1 in 1000 people)

- chest pain due to angina pectoris.

Other possible side effects

Common (may affect up to 1 in 10 people)

- headache
- sleepiness.

Uncommon (may affect up to 1 in 100 people)

- irritability, nervousness, restlessness, anxiety
- insomnia, abnormal dreams, nightmares, night sweats
- migraine, dizziness, nausea
- tiredness (and lack of energy), restlessness associated with increased activity
- high blood pressure
- abdominal pain, upper abdominal pain, indigestion
- mouth ulcers, dry mouth
- changes in the composition of your blood which can cause yellowing of the skin and eyes
- skin problems (dermatitis, itching, rash, general itching, dry skin)
- pain in arms and legs
- excretion of glucose in the urine, too much protein in the urine
- menopausal symptoms
- feeling of weakness, chest pain
- liver test abnormalities
- weight gain.

Rare (may affect up to 1 in 1000 people)

- shingles (herpes zoster)
- reduced number of white blood cells in the blood
- reduced number of platelets in the blood
- low levels of calcium or sodium in the blood
- high levels of fats in the blood
- altered mood, aggression, restlessness, crying, stress symptoms, feeling confused (disoriented), early morning awakening, increased sex drive (increased libido), depressed mood, depression
- fainting, memory impairment, attention disorder, dreamy state, unpleasant feeling in the legs (restless legs syndrome), poor sleep quality, “pins and needles” feeling (paresthesia)
- impaired visual acuity, blurred vision, watery eyes
- a feeling of dizziness or spinning (vertigo), dizziness when getting up or sitting down
- feeling your heartbeat
- hot flushes
- acid reflux, gastrointestinal disorder, blistering in the mouth, tongue ulceration, gastrointestinal upset, vomiting, abnormal bowel sounds, wind (flatulence), increased salivation, bad breath, abdominal discomfort, gastric disorder, inflammation of the gastric mucosa
- skin problems (eczema, redness, hand dermatitis, psoriasis, rash generalized, itchy rash), nail disorders
- joint inflammation (arthritis), muscle cramps, neck pain, night cramps
- increased amounts of urine, red blood cells in the urine, urination at night
- prolonged erection - that might be painful - without sexual stimulation, inflammation or swelling of the prostate
- tiredness, pain, thirst
- increased liver enzymes, abnormal blood electrolytes and abnormal laboratory tests.

Not known (frequency cannot be estimated from the available data)

- high blood sugar level
- abnormal milk secretion.

**Reporting of side effects**

If you or your child 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 [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 {Invented 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 bottle after EXP. The expiry date refers to the last day of that month.

{Invented name} can be used up to 6 months after opening the bottle.

This medicine does not require any special temperature storage conditions. Store in the original bottle in order to protect from light.

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 are there to protect the environment.

**6. Contents of the pack and other information**

**What {Invented name} contains**

- The active substance is melatonin.
- The other ingredients are glycerol (E 422), methyl parahydroxybenzoate (methylparaben) (E 218), potassium sorbate (E 202), hydrochloric acid (for pH adjustment) and purified water.

**What {Invented name} looks like and contents of the pack**

{Invented name} is a clear, colourless to slightly yellowish oral solution.

100 ml of solution in an amber glass bottle with a white cap of aluminium. A dosing syringe is packed with the bottle. The volume of the syringe is 5 ml with a graduation scale of 0.1 ml.

Pack size: 1 x 100 ml

**Marketing Authorisation Holder and Manufacturer**

<to be completed nationally>

**This leaflet was last revised on**  
28-NOV-2025