

## Package leaflet: Information for the patient

### Melatonin Orion 3 mg tablets

### Melatonin Orion 5 mg tablets

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

### 1. What Melatonin Orion is and what it is used for

Melatonin Orion contains the active substance melatonin which belongs to a group of natural hormones produced by the body. Melatonin helps regulate the body's day and night rhythm.

Melatonin Orion is used for:

- Short-term treatment of jet lag in adults from the age of 18 years. Jet lag refers to symptoms caused by the time difference when travelling through several time zones – travelling east or west.
- Insomnia in children and adolescents (6 to 17 years old) with ADHD where other healthy sleeping routines has not worked well enough.

Melatonin Orion might be suitable to adult travellers flying across 5 or more time zones, particularly in an easterly direction, and if they have experienced jet lag symptoms on previous journeys.

### 2. What you need to know before you take Melatonin Orion

#### Do not take Melatonin Orion

- if you are allergic to melatonin or any of the other ingredients of this medicine (listed in section 6).

#### Warnings and precautions

Talk to a doctor or pharmacist before taking Melatonin Orion if you have:

- diabetes or impaired glucose tolerance, as this medicine may increase the level of glucose in your blood
- liver or kidney disease
- an autoimmune disease (where the body is 'attacked' by its own immune system)
- epilepsy. Melatonin may increase the seizure frequency in patients with epilepsy.
- or if you are elderly.

Smoking may make Melatonin Orion less effective, because the components of tobacco smoke can increase the breakdown of melatonin by the liver.

Women of childbearing potential should use contraception during treatment with Melatonin Orion. See section “Pregnancy and breast-feeding” for more information. This medicinal product may however be affected by certain contraceptives, see the section “Other medicines and Melatonin Orion” for more information.

### **Children and adolescents**

This medicine is not recommended for children or adolescents below 18 years of age in short-term treatment of jet lag. Do not give this medicine to children below 6 years of age.

### **Melatonin Orion with food and alcohol**

Food should not be consumed 2 hours before or 2 hours after intake of Melatonin Orion tablets. Do not drink alcohol before, during or after taking Melatonin Orion, as it may reduce the effect of melatonin.

### **Other medicines and Melatonin Orion**

Tell a doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including non-prescription medicines.

If Melatonin Orion is taken at the same time as the following medicines, it can affect the way that Melatonin Orion or the other medicine works:

- warfarin and other anticoagulants, e.g. dabigatran, rivaroxaban, apixaban, edoxaban (used to prevent blood clotting) – INR (blood clotting test) may be necessary to verify more specifically
- antidepressants such as fluvoxamine and imipramine
- ciprofloxacin, norfloxacin and rifampicin (used in the treatment of bacterial infections)
- carbamazepine and phenytoin (used in the treatment of epilepsy)
- 5- or 8-methoxypsoralen (5 and 8-MOP) (used in the treatment of skin diseases such as psoriasis)
- medicines for pain and inflammation (nonsteroidal anti-inflammatory medicines, e.g. acetylsalicylic acid and ibuprofen)
- benzodiazepines and non-benzodiazepine hypnotics (medicines used to induce sleep such as zaleplon, zolpidem and zopiclone)
- cimetidine for ulcers
- verapamil (heart conditions)
- antihypertensives (nifedipine, beta-blockers)
- thioridazine (for schizophrenia)
- contraceptives containing ethinylestradiol and gestagen
- hormone replacement therapy due to menopause problems.

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

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*

Fertile women should use contraceptives under the Melatonin Orion treatment. This medicinal product may however be affected by certain contraceptives, see the section “Other medicines and Melatonin Orion” for more information. Discuss with a doctor for choice of contraceptives.

#### *Pregnancy*

Melatonin Orion 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*

Melatonin Orion is not recommended if you are breast-feeding. Melatonin is passed into human milk, and a risk to the breast-fed child cannot be excluded.

### **Driving and using machines**

Melatonin Orion 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.

### **Excipients**

This medicine contains less than 1 mmol (23 mg) sodium per tablet, that is to say essentially 'sodium-free'.

## **3. How to take Melatonin Orion**

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

### **Adults with jet lag**

The standard dose is one 3 mg tablet taken once a day for a maximum of 4 days. Take the tablet at local bedtime, starting on the arrival at destination.

If the standard dose of 3 mg does not adequately alleviate symptoms you can take one 5 mg tablet instead. The 5 mg tablet should not be taken in addition to the 3 mg tablet (i.e. not on the same day), but a higher dose may be taken on the following days.

Maximal daily dose is 5 mg. Maximum duration of treatment is 4 days.

Timing of melatonin intake is important. The dose should be taken at bedtime (in the local time). The tablets should not be taken before 20:00 hr or after 04:00 hr.

### **Children and adolescents aged 6–17 years with insomnia associated with ADHD**

Melatonin treatment should be titrated up to the lowest effective dose. Melatonin Orion can be used when the lowest effective dose has been established to be 3 or 5 mg taken 30–60 minutes before bedtime.

Treatment should be followed up regularly by a doctor (your doctor tells you how often) to see if it is still appropriate.

The tablet can be crushed before intake and mixed with cold water.

Food should not be consumed 2 hours before or 2 hours after intake of Melatonin Orion tablets.

### **If you take more Melatonin Orion than you should**

If you or your child has accidentally taken too much medicine or if a child or adolescent has ingested the medicine by mistake, contact a doctor or hospital to assess the risks and to get additional instructions.

Taking more than the recommended daily dose may make you feel drowsy.

### **If you forget to take Melatonin Orion**

If you forget to take a 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 Melatonin Orion**

There are no known harmful effects if treatment is interrupted or ended. The use of Melatonin Orion 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 experience any of the following serious side effects, stop taking Melatonin Orion and contact a doctor immediately:

Uncommon (may affect up to 1 in 100 people):

- chest pain.

Rare (may affect up to 1 in 1 000 people):

- loss of consciousness or fainting
- severe chest pain due to angina
- feeling your heartbeat
- depression
- visual impairment
- disorientation
- vertigo (a feeling of dizziness or “spinning”)
- presence of blood in the urine
- reduced number of white blood cells in the blood
- reduced blood platelets, which increases risk of bleeding or bruising
- psoriasis.

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

- hypersensitivity reaction
- swelling of the skin.

If you experience any of the following non-serious side effects contact your doctor and/ or seek medical advice:

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
- migraine, dizziness, nausea
- lethargy (tiredness) and lack of energy, restlessness associated with increased activity
- high blood pressure
- abdominal pain, indigestion, mouth ulceration, dry mouth
- changes in the composition of your blood which can cause yellowing of the skin and eyes
- inflammation of the skin, itching, rash, dry skin, night sweats
- pain in arms and legs
- excretion of glucose in the urine, excess proteins in the urine
- menopausal symptoms
- feeling of weakness
- weight gain.

Rare (may affect up to 1 in 1 000 people):

- shingles
- low calcium or sodium levels in the blood

- high level of blood fats
- altered mood, aggression, restlessness associated with increased activity, crying, stress symptoms, early morning awakening, increased sex drive, depressed mood
- memory impairment, disturbance in attention, dreamy state, restless legs syndrome, poor quality sleep, 'pins and needles' feeling, hallucinations
- blurred vision, watery eyes
- dizziness when standing or sitting
- hot flushes
- acid reflux, gastrointestinal disorder, blistering in the mouth, tongue ulceration, stomach upset, vomiting, abnormal bowel sounds, wind, excess saliva production, bad breath, abdominal discomfort, inflammation of the stomach lining
- eczema, skin rash, hand dermatitis, itchy rash, nail disorder
- arthritis, muscle spasms, neck pain, night cramps
- passing large volumes of urine, urinating during the night
- prolonged erection - that might be painful - without sexual stimulation, inflammation of the prostate gland
- tiredness, pain, thirst
- increased liver enzymes, abnormal blood electrolytes and abnormal laboratory tests.

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

- swelling of face, swelling of mouth, swelling of tongue
- abnormal milk secretion
- hyperglycaemia.

#### Side effects in children and adolescents

A low frequency of in general mild adverse reactions have been reported in children and adolescents. The most common side effects have been headache, hyperactivity, dizziness, and abdominal pain. No serious side effects have been observed.

#### **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 the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://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 Orion**

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 label, blister and carton. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Blister: Keep the blister in the outer carton in order to protect from light.

Bottle: Store in the original package 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 will help protect the environment.

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

### **What Melatonin Orion contains**

- The active substance is melatonin 3 mg or 5 mg.
- The other ingredients are magnesium stearate (E470b), silica colloidal anhydrous (E551), cellulose microcrystalline (E460), croscarmellose sodium (E468).

### **What Melatonin Orion looks like and contents of the pack**

3 mg: White to whitish coloured round biconvex tablets, with approximate size of 6.0 x 2.5 mm.

5 mg: White to whitish coloured round biconvex tablets, with approximate size of 7.0 x 3.2 mm. A scoreline on both sides. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Melatonin Orion 3 mg and 5 mg tablets are available in a carton containing PVC/PE/PVDC/AL blister packs of 10, 30, 50 and 60 tablets.

Melatonin Orion 3 mg and 5 mg tablets are available in HDPE bottles closed with HDPE closures.

Pack sizes:

3 mg: 100 tablets.

5 mg: 100 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

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