

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

### **Melatonin 2 mg, 3 mg, 5 mg Hard Capsules** 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 Hard Capsules are and what they are used for
2. What you need to know before you use Melatonin Hard Capsules
3. How to use Melatonin Hard Capsules
4. Possible side effects
5. How to store Melatonin Hard Capsules
6. Contents of the pack and other information

The name of your medicine is Melatonin 2mg, 3mg or 5mg hard capsules. It will be referred to as Melatonin hard capsules for ease of use hereafter.

#### **1. What Melatonin Hard Capsules are and what they are used for**

Melatonin Hard Capsules contain the active substance melatonin. Melatonin Hard Capsules can be used for treatment of jet-lag in adults. Jet-lag can be recognized by sleep disturbances, daytime tiredness, fatigue, mild mental impairment, irritability and digestive system disturbances experienced after flying.

##### *How Melatonin Hard Capsules work*

Melatonin is a hormone produced by the body that synchronizes the body's biological day-and-night rhythm. The biological rhythm can be disturbed by travelling across time zones. This is known as jet-lag. The symptoms and their severity vary between individuals, but are generally worse and last longer the more time zones are crossed. Melatonin Hard Capsules can help restore the normal day-and-night rhythm and reduce the symptoms.

You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

#### **2. What you need to know before you use Melatonin Hard Capsules**

##### **Do not take Melatonin Hard Capsules**

- 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 Melatonin Hard Capsules:

- 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 Hard Capsules as components of tobacco smoke can increase the breakdown of melatonin by the liver.

### **Children and adolescents**

Do not give this medicine to children and adolescents between 0 and 18 years as its safety and efficacy are unknown.

### **Other medicines and Melatonin Hard Capsules**

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
- Estrogens (used in contraceptives or hormone replacement preparations), as estrogens 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, and 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 Hard Capsules 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 of jet-lag (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 Hard Capsules are 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. If you are woman of childbearing potential you have to use contraception.

### Breast-feeding

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

### Fertility

Melatonin Hard Capsules are 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 Hard Capsules 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.

### **Melatonin 2 mg Hard Capsules and Melatonin 5 mg Hard Capsules contain sodium.**

These medicines contain less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

## **3. How to use Melatonin Hard Capsules**

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

The recommended dose for adults, including the elderly, is 3 mg daily for a maximum of 5 days. The dose may be increased to 5 mg or 6 mg (2 capsules of 3 mg taken simultaneously) when the effect of Melatonin Hard Capsules is inadequate. A lower dose of 2 mg may be sufficient for some individuals.

The first dose should be taken on arrival at destination at your usual bed-time. Intake on the following days should also be at your usual bed-time. The capsules should not be taken before 20:00 hr or after 04:00 hr.

The capsules should be swallowed whole with water or other liquid (e.g. milk, fruit juice). Food should not be consumed 2 hours before or 2 hours after intake of Melatonin Hard Capsules.

Melatonin Hard Capsules may be taken for a maximum of 16 treatment periods per year.

### **If you take more Melatonin Hard Capsules than you should**

If you have taken more Melatonin Hard Capsules 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 Hard Capsules**

If you forget to take a capsule 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 missed dose.

## **If you stop taking Melatonin Hard Capsules**

If you stop taking Melatonin Hard Capsules, 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

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

- Hypersensitivity reactions
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: [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 Hard Capsules**

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 below 25°C.

Keep in the outer carton 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 Hard Capsules contain**

#### Melatonin 2 mg Hard Capsules

- Each capsule of Melatonin 2 mg Hard Capsules contains 2 mg of the active substance melatonin.
- The other ingredients are: Cellulose, Microcrystalline, Povidone K30, Maltodextrin and Magnesium Stearate.
- The capsule shell of Melatonin 2 mg Hard Capsules contains: Gelatin, Titanium Dioxide (E171) and indigotine – FD&C blue 2 (including sodium) (E132).

#### Melatonin 3 mg Hard Capsules

- Each capsule of Melatonin 3 mg Hard Capsules contains 3 mg of the active substance melatonin.
- The other ingredients are: Cellulose, Microcrystalline, Povidone K30, Maltodextrin and Magnesium Stearate.
- The capsule shell of Melatonin 3 mg Hard Capsules contains: Gelatin and Titanium Dioxide (E171).

#### Melatonin 5 mg Hard Capsules

- Each capsule of Melatonin 5 mg Hard Capsules contains 5 mg of the active substance melatonin.
- The other ingredients are: Cellulose, Microcrystalline, Povidone K30, Maltodextrin and Magnesium Stearate.
- The capsule shell of Melatonin 5 mg Hard Capsules contains: Gelatin, Titanium Dioxide (E171) and indigotine – FD&C blue 2 (including sodium) (E132).

### **What Melatonin Hard Capsules look like and contents of the pack**

Melatonin 2 mg Hard Capsules: are size 3, opaque hard gelatin capsules, with a white body and light blue cap.

Melatonin 3 mg Hard Capsules: are size 3, opaque hard gelatin capsules, with a white body and white cap.

Melatonin 5 mg Hard Capsules: are size 1, opaque hard gelatin capsules, with a light blue body and light blue cap.

They are packed in PVC/PVDC/aluminium blisters. Each blister contains 7 or 10 capsules.

Pack sizes: 10, 14, 28, 30 hard capsules.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

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### **Manufacturer**

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