

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Circadin 2 mg prolonged-release tablets**

Melatonin

**Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Circadin is and what it is used for
2. Before you take Circadin
3. How to take Circadin
4. Possible side effects
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6. Further information

### **1. WHAT CIRCADIN IS AND WHAT IT IS USED FOR**

The active substance of Circadin, melatonin, belongs to a natural group of hormones produced by the body.

Circadin is used as monotherapy for the short-term treatment of primary insomnia (difficulty in getting to sleep or staying asleep, or poor quality of sleep for at least one month), characterised by poor quality of sleep in patients aged 55 years and older.

### **2. BEFORE YOU TAKE CIRCADIN**

#### **Do not take Circadin**

- if you are allergic (hypersensitive) to melatonin or any of the other ingredients of Circadin.

#### **Take special care with Circadin**

- if drowsiness is likely to cause a risk to your safety;
- if you suffer from any liver problems;

- if you suffer from kidney problems;
- if you suffer from any autoimmune disease (where the body is 'attacked' by its own immune system).

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription BEFORE you start the treatment as they may affect the action of Circadin. These medicines include hypnotics and tranquilisers (e.g. benzodiazepines), fluvoxamine, thioridazine and imipramine (used to treat depression or psychiatric problems), oestrogen (contraceptives or hormone replacement therapy), cimetidine and psoralens (used to treat skin problems e.g. psoriasis).

### **Taking Circadin with food and drink**

Take Circadin after you have eaten. Do not drink alcohol before, during or after taking Circadin.

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

Ask your doctor or pharmacist for advice before taking any medicine.

It is not recommended to take Circadin if you are pregnant or suspect that you may be pregnant. It is not recommended to take Circadin if you are breast feeding.

### **Driving and using machines**

Circadin may cause drowsiness. If you are affected, you should not drive or operate machinery. If you suffer from continued drowsiness, then you should consult your doctor.

### **Important information about some of the ingredients of Circadin**

Each prolonged-release tablet contains 80 mg of lactose-monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. HOW TO TAKE CIRCADIN**

Always take Circadin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The dose is one Circadin tablet taken daily by mouth, after food, 1-2 hours before bedtime, for 3 weeks. You should swallow the tablet whole. Circadin tablets should not be crushed or cut in half.

### **If you take more Circadin than you should**

If you have accidentally taken too much of your medicine, contact your doctor or pharmacist as soon as possible.

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

### **If you forget to take Circadin**

If you forget to take your tablet, take another as soon as you remember, before going to sleep, or wait until it is time to take your next dose, then go on as before.

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

### **If you stop taking Circadin**

There are no known harmful effects if treatment is interrupted or ended early. The use of Circadin is not known to cause any withdrawal effects after treatment completion.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Circadin can cause side effects, although not everybody gets them. The following events are considered to be uncommon (i.e. likely to occur in fewer than 1 in 100 patients):

Irritability, nervousness, restlessness, insomnia, abnormal dreams, migraine, psychomotor hyperactivity (restlessness associated with increased activity), dizziness, somnolence (tiredness), abdominal pain, constipation, dry mouth, hyperbilirubinaemia (changes in the composition of your blood which could cause yellowing of the skin or eyes (jaundice), hyperhidrosis (excessive sweating), asthenia (feeling of weakness) and weight increase.

The following events are considered to be rare (i.e., likely to occur in fewer than 1 in 1,000 patients):

Herpes Zoster (shingles), leukopenia, thrombocytopenia, hypertriglyceridaemia, altered mood, aggression, agitation, crying, early morning awakening, increased libido (increased sex drive), memory impairment, disturbance in attention, poor quality sleep, reduced visual acuity (visual

impairment), blurred vision, increased lacrimation (watery eyes), positional vertigo (dizziness when standing), hot flushes, gastrointestinal upset, vomiting, abnormal bowel sounds, flatulence (wind), salivary hypersecretion (excess saliva production), halitosis (bad breath), abnormal liver function test (increased liver enzymes), eczema, erythema (skin rash), pruritic rash (itchy rash), pruritus (itching), dry skin, nail disorder, night sweats, muscle cramp, neck pain, priapism (increased duration of erection) and fatigue (tiredness).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **5. HOW TO STORE CIRCADIN**

Keep out of the reach and sight of children.

Do not use Circadin after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **6. FURTHER INFORMATION**

What Circadin contains

- The active substance is melatonin. Each prolonged-release tablet contains 2 mg melatonin.

- The other ingredients are ammonio methacrylate copolymer type B, calcium hydrogen phosphate dihydrate, lactose monohydrate, silica (colloidal anhydrous), talc and magnesium stearate.

### **What Circadin looks like and contents of the pack**

Circadin 2 mg prolonged-release tablets are available as white to off-white round bi-convex shaped tablets. Each carton of tablets contains one blister strip of 20 or 21 tablets. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### Marketing Authorisation Holder:

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#### Manufacturer:

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This leaflet was last approved in {MM/YYYY}.

Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.emea.europa.eu>

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder

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