

**Package Leaflet:
Information for the patient**

circadin® 2 mg
prolonged-release 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 Circadin is and what it is used for
2. What you need to know before you take Circadin
3. How to take Circadin
4. Possible side effects
5. How to store Circadin
6. Contents of the pack and other 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 on its own for the short-term treatment of primary insomnia (persistent difficulty in getting to sleep or staying asleep, or poor quality of sleep) in patients aged 55 years and older. 'Primary' means that the insomnia does not have any identified cause, including any medical, mental or environmental cause.

2. What you need to know before you take Circadin

Do not take Circadin

- 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 Circadin.

- If you suffer from liver or kidney problems. No studies on the use of Circadin in people with liver or kidney diseases have been performed, you should speak to your doctor before taking Circadin as its use is not recommended.
- If you have been told by your doctor that you have an intolerance to some sugars.
- If you have been told you suffer

skin disorders e.g. psoriasis), cimetidine (used in the treatment of stomach problems such as ulcers), quinolones and rifampicin (used in the treatment of bacterial infections), oestrogens (used in contraceptives or hormone replacement therapy) and carbamazepine (used in the treatment of epilepsy).

- Adrenergic agonists/antagonists (such as certain types of medicines used to control blood pressure by constricting blood vessels, nasal decongestants, blood pressure lowering medicines), opiate agonists/antagonists (such as medicinal products used in the treatment of drug addiction), prostaglandin inhibitors (such as nonsteroidal anti-inflammatory medicines), antidepressant medication, tryptophan and alcohol.
- Benzodiazepines and non-benzodiazepine hypnotics (medicines used to induce sleep such as zaleplon, zolpidem and zopiclone)
- Thioridazine (for the treatment of schizophrenia) and imipramine (for the treatment of depression).

Circadin with food, drink and alcohol

Take Circadin after you have eaten. Do not drink alcohol before, during or after taking Circadin, because it reduces the effectiveness of Circadin.

Pregnancy and breast-feeding

Do not take Circadin if you are pregnant, think you may be pregnant, trying to become pregnant or breast-feeding. Ask your doctor or pharmacist for advice before taking this medicine.

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.

Circadin contains lactose monohydrate

Circadin contains 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 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 is one Circadin tablet (2 mg) taken daily by mouth, after food, 1-2 hours before bedtime. This dosage may be continued for up to thirteen weeks. You must talk to a doctor if you do not feel better or if you feel worse after 21 days

cause side effects, although not everybody gets them.

If you experience any of the following serious side effects, stop taking the medicine and contact your doctor

immediately:

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

- Chest pain

Rare: (may affect up to 1 in 1000 people)

- Loss of consciousness or fainting
- Severe chest pain due to angina
- Feeling your heartbeat
- Depression
- Visual impairment
- Blurred vision
- Disorientation
- Vertigo (a feeling of dizziness or "spinning")
- Presence of red blood cells in the urine
- Reduced number of white blood cells in the blood
- Reduced blood platelets, which increases risk of bleeding or bruising
- psoriasis

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

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

Irritability, nervousness, restlessness, insomnia, abnormal dreams, nightmares, anxiety, migraine, headache, lethargy (tiredness, lack of energy), restlessness associated with increased activity, dizziness, tiredness, high blood pressure, upper abdominal pain, indigestion, mouth ulceration, dry mouth, nausea, changes in the composition of your blood which could cause yellowing of the skin or eyes, inflammation of the skin, night sweats, itching, rash, dry skin, pain in extremities, menopausal symptoms, feeling of weakness, excretion of glucose in the urine, excess proteins in the urine, abnormal liver function and weight increase.

Rare: (may affect up to 1 in 1000 people)

Shingles, high level of fatty molecules in the blood, low serum calcium levels in the blood, low sodium levels in the blood, altered mood, aggression, agitation, 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, watery eyes, dizziness when standing or sitting, hot flushes, acid reflux, stomach disorder, blistering in the mouth, tongue ulceration, stomach upset, vomiting, abnormal bowel sounds, wind, excess saliva production, bad breath, abdominal discomfort, gastric