

Package leaflet: information for the patient
Circadin 2 mg, prolonged-release tablets
Melatonin

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may be harmful to others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect that is not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

1. What is Circadin and what is it used for?
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1. What is Circadin and what is it used for?

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

Circadin is used without other means for short-term treatment of patients 55 years and older with primary insomnia (persistent problems with falling asleep or staying asleep, or poor sleep quality). 'Primary' means that there is no established cause for the insomnia, not medical, not mental, and not caused by the environment. When should you not use Circadin or be extra careful?

2. When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in

- section 6. section 6.

Contact your doctor or pharmacist before using this medicine.

If you have a liver or kidney condition. No research has been conducted on the use of

- Circadin in people with liver or kidney disease. Therefore, discuss it with your doctor before you use Circadin, as the use of Circadin in the presence of liver or kidney disease is not recommended. If your doctor has told you that you cannot tolerate certain sugars.
- If your doctor has told you that you have an autoimmune disease (where the body is
- If your doctor has told you that you have an autoimmune disease (where the body is 'attacked' by the body's own immune system). No research has been conducted on the use of Circadin in people with an autoimmune disease. Therefore, discuss it with your

doctor before If you use Circadin, because the use of Circadin in the presence of an autoimmune disease is not recommended.

- Using Circadin may make you feel drowsy. If this is the case, then you should be cautious as your ability to perform tasks, such as driving a vehicle, may be impaired.
- If you smoke, the effectiveness of Circadin may be reduced because components of tobacco smoke can increase the breakdown of melatonin by the liver.

Children and adolescents up to 18 years

Do not give this medicine to children and adolescents from 0 to 18 years, as its use in this age group has not been studied and its effect is therefore unknown. Another medicine with melatonin may be more suitable for administration to children and adolescents from 2 to 18 years. Consult your doctor or pharmacist for advice.

Are you taking any other medicines?

Are you taking any other medicines besides Circadin, or have you recently taken any or is there a possibility that you will take other medicines in the near future? Then tell your doctor or pharmacist. These include:

Fluvoxamine (used for the treatment of depression and obsessive compulsive disorder (OCD)), psoralen (used in the treatment of skin conditions such as psoriasis), cimetidine (used in the treatment of stomach problems such as ulcers), quinolones and rifampicin (used in the treatment of a bacterial infection), estrogens (used in contraceptives and in hormone replacement therapy) and carbamazepine (which is used in the treatment of epilepsy).

Adrenergic agonists/antagonists (such as certain types of drugs used for regulating blood pressure by constricting blood vessels, nasal decongestants, which are agents that reduce swelling in the nose, and antihypertensive drugs), opiate agonists/antagonists (such as drugs used in the treatment of drug addiction), prostaglandin inhibitors (such as non-steroidal anti-inflammatory drugs), antidepressants, tryptophan, and alcohol.

Benzodiazepines and non-benzodiazepine hypnotics (drugs used to induce sleep, such as zaleplon, zolpidem, and zopiclone)

Thioridazine (for the treatment of schizophrenia) and imipramine (for the treatment of depression).

What should you be aware of with food, drink, and alcohol?

Use Circadin after you have eaten. Do not use alcohol before, during, or after using Circadin, as this reduces the effectiveness of Circadin.

Pregnancy and breastfeeding

Do not use this medicine if you are pregnant, think you may be pregnant, want to become pregnant, or are breastfeeding. Contact your doctor or pharmacist before using this medicine.

Driving and using machines

Circadin can cause drowsiness. If this is the case for you, you must not drive a vehicle or operate machinery. If you are persistently drowsy, you should consult your doctor.

Circadin contains lactose monohydrate

Circadin contains lactose monohydrate. If your doctor has told you that you do not tolerate certain sugars, contact your doctor before using this medicine.

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

The recommended dosage is one Circadin 2 mg tablet once daily, 1 to 2 hours before going to bed and after some food taken orally. This dose can be maintained for up to thirteen weeks. maintained.

broken in half. Have you used too much of this medicine?

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

Have you forgotten to use this medicine?

If you forget to take a tablet, take it as soon as you remember, before going to sleep, or wait until it is time to take your next dose and then just continue with that. sleep, or wait until it is time to take your next dose and then just continue with that next dose.

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

If you stop using this medicine

There are no known harmful effects if the treatment is interrupted or terminated early. Circadin is not known to cause withdrawal symptoms after the treatment is completed.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody experiences them.

If you experience any of the following side effects, stop using the medicine and contact your doctor immediately.

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

Chest pain

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

Unconsciousness or fainting

Severe chest pain due to angina pectoris

Palpitations

Depression
Visual impairment
Blurred vision
Disorientation
Vertigo (a feeling of dizziness or spinning)
Presence of red blood cells in the urine
Decrease in the number of white blood cells in the blood
Decrease in the number of platelets, increasing the risk of bleeding or bruising increases
Psoriasis

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

Sometimes: (may occur in less than 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, fatigue, high blood pressure, upper abdominal pain, indigestion, mouth ulcers, dry mouth, nausea, changes in the composition of your blood, which can cause yellowing of your skin or eyes, skin inflammation, night sweats, itching, rash, dry skin, limb pain, menopausal symptoms, feeling of weakness, excretion of glucose in the urine, too much protein in the urine, abnormal liver function values, and weight gain.

Rarely: (may occur in less than 1 in 1000 people)

Shingles, high concentration of fat molecules in the blood, low calcium levels in the blood serum, low sodium levels in the blood, mood changes, aggression, agitation, crying, symptoms of stress, early morning awakening, increased libido, depressed mood, memory disorder, attention disorder, dreamy state, restless legs syndrome, poor sleep quality, tingling, watery eyes, dizziness when standing or sitting, hot flashes, acid reflux, stomach disorder, mouth ulcers, tongue ulcers, stomach complaints, vomiting, abnormal bowel sounds, flatulence, excessive saliva production, bad breath, abdominal complaints, stomach disorder, inflammation of the stomach lining, eczema, skin rash, skin inflammation of the hand, itchy skin rash, nail disorder, joint inflammation, muscle spasms, neck pain, nocturnal cramps, longer erection duration which can be painful, inflammation of the prostate gland, fatigue, pain, thirst, passing large amounts of urine, needing to urinate at night, increased liver enzyme levels, abnormal electrolyte levels in the blood and abnormal laboratory tests.

Frequency not known: (cannot be estimated from the available data)

Hypersensitivity reaction, swelling of the mouth or tongue, swelling of the skin and abnormal milk secretion.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as mentioned in Appendix V. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How should you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the box after EXP. It includes a month and a year. The last day of that month is the expiry date.

Store below 25°C. Keep in the original packaging to protect from light.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed in a responsible manner and will not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is melatonin. Each prolonged-release tablet contains 2 mg melatonin.
- The other substances (excipients) in this medicine are ammonio methacrylate copolymer type B, calcium hydrogen phosphate dihydrate, lactose monohydrate, silicon dioxide (colloidal anhydrous), talc, and magnesium stearate.

What does Circadin look like and what is in a package?

Circadin 2 mg prolonged-release tablets are available as white to off-white, round biconvex tablets. Each package of tablets consists of a blister strip with 7, 20, or 21 tablets, two blister strips each with 15 tablets (package of 30 tablets) or otherwise from a perforated unit blister pack with 30 x 1 tablets. Not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder:

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Other sources of information

More information about this medicine is available on the website of the European Medicines Agency <http://www.ema.europa.eu>