Circadin 2 mg
prolonged release tablets
Melatonin

Read all of this leaflet carefully before you start taking this medicinal product. It contains important information for you.

1. What Circadin is and what it is used for

Circadin is used on its own for the treatment of depression (shizophrenia) and insomnia (persistent difficulty in falling or staying asleep, or getting to sleep). It may also be used in patients aged 55 years and older. ‘Primary’ insomnia (poor quality of sleep) in patients getting to sleep or staying asleep, or insomnia (persistent difficulty in falling asleep) in patients aged 55 years and older. ‘Primary’ insomnia (poor quality of sleep) in patients getting to sleep or staying asleep, or insomnia (persistent difficulty in falling asleep) in patients aged 55 years and older.

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 medicinal product (see section 4).

Warnings and precautions

Talk to your doctor or pharmacist before taking Circadin:

- if you have been told you suffer from any of the conditions listed in this leaflet. You can also report side effects directly via:
- if you have any further questions, ask your doctor or pharmacist.

3. How to take Circadin

Always take this medicine exactly as your doctor or pharmacist has told you. The recommended dose is one Circadin tablet (2 mg) taken daily by mouth, after meals or 1 to 2 hours before bedtime. This dosage may be continued for up to thirteen 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 your tablets:

If you forget to take your tablet, take another as soon as you remember, before going to bed, 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 stopped or ended early. The use of Circadin is not known to cause any withdrawal effects after short term 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 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
- Swelling of the legs
- Visual impairment
- Blurred vision
- Dizziness
- Vertigo (a feeling of dizziness or “spinning”)
- Presence of red blood cells in the urine
- Reduced number of white blood cells
- Reduced blood platelets, which increases risk of bleeding or bruising
- Psychiatry

If you experience any of the following non-serious side effects contact your doctor:

- Feelings of nervousness, restlessness, insomnia, abnormal dreams, nightmares, anxiety, migraine, headache, feeling tired (lack of energy), restlessness associated with increased activity, dizziness, tiredness, hiccups, sweating, upper abdominal pain, indigestion, mouth ulceration, dry mouth, nausea, changes in taste sensation, confusion, abdominal pain, bloating, incontinence of urine, inflammation of the skin, skin rashes, itching, rash, dry skin, pain in extremities, menstrual disorders, feelings of weakness, shortness of breath, increased sweating, depressed mood, memory impairment, disturbance in attention, dreamy state, restless legs, tongue, dreamy state, restless legs syndrome, poor quality sleep, ‘pins and needles’ feeling, watery eyes, diziness

To report side effects

Reporting of side effects

If you experience any of the following rare side effects contact your doctor:

- Abnormal blood electrolytes and acid-base changes, e.g. abnormal blood calcium, potassium, magnesium levels in the blood, low sodium levels in the blood, abnormal blood glucose levels in the urine, abnormal blood ketone levels, abnormal blood triglyceride levels, abnormal blood cholesterol levels, abnormal blood ferritin levels, abnormal blood vitamin B12 levels, abnormal blood creatinine levels, abnormal blood inorganic phosphorus levels, abnormal blood iron levels, abnormal blood aspartate transaminase levels, abnormal blood alanine transaminase levels, abnormal blood alkaline phosphatase levels, abnormal blood bilirubin levels, abnormal blood bilirubin conjugated levels, abnormal blood albumin levels, abnormal blood haemoglobin levels, abnormal blood haematocrit levels, abnormal blood white blood cell levels, abnormal blood red blood cell levels, abnormal blood platelet levels, abnormal blood lymphocyte levels, abnormal blood monocyte levels, abnormal blood eosinophil levels, abnormal blood neutrophil levels, abnormal blood mean cell volume levels, abnormal blood mean cell haemoglobin levels, abnormal blood mean cell haemoglobin concentration levels, abnormal blood red blood cell distribution width levels.

If you have been told you suffer from any of the conditions listed in this leaflet. You can also report side effects directly via:

- 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:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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Contents of the pack and other environmental measures will help to protect the medicines you no longer use. These wastewaters or household waste. Ask Do not throw away any medicines via from light.

Do not store above 25°C. Store in the last day of that month. Do not use this medicine after the carton (EXP). The expiry date refers to keep this medicine out of the reach of children.

5. How to store Circadin

Safeguard your medicines and reach of children. Keep this medicine out of the sight and reach of children.

6. Contents of the pack and other information

What Circadin contains – The active substance is melatonin. Each prolonged-release tablet contains 2mg 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 2mg prolonged-release tablets are available as white to off-white round biconvex shaped tablets. Each carton of tablets contains one blister strip of 7, 20 or 21 tablets, or alternatively in a carton containing two blister strips of 15 tablets each (30 tablet pack). Not all pack sizes may be marketed.

Marketing Authorisation Holder

Marketing Authorisation Holder: RAD Neurim Pharmaceuticals EEC Limited One Forbury Square The Forbury Reading Berkshire RG1 3EB United Kingdom e-mail: neurim@neurim.com

Manufacturer

Sites responsible for Batch Release in the EEA: Iberfar - Industria Farmaceutica S.A. Rua Conselheiro Pedroso, n.0 121-123 Queluz de Baixo Barcarena, 2745-557 Portugal For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder This leaflet was last revised in 07/2015. Other sources of information Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu

Authorisation Holder representative of the Marketing Authorisation Holder:

RAD Neurim Pharmaceuticals EEC Limited

Marketing Authorisation Holder pack sizes may be marketed.

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