Prescribing Information for Circadin® 2mg tablets. Please refer to the full Summary of Product Characteristics before prescribing.
Presentation: Circadin 2mg prolonged-release tablets containing 2mg melatonin.
Indication: Monotherapy for the short-term treatment of primary insomnia characterised by poor quality sleep in patients aged 55 or over.
Dosage and administration: 2mg orally once daily, 1-2 hours before bedtime and after food. Swallow whole do not crush or chew. This dosage may be continued for up to thirteen weeks. **Children and adolescents (<18 years)**: Safety and efficacy not yet established.
Contraindications: Hypersensitivity to the active substance or to any excipients.
Special warnings and precautions for use: Use caution when administered to patients with renal insufficiency. Not recommended for use in patients with hepatic impairment. Circadin may cause drowsiness, therefore use with caution if the effects of drowsiness are likely to be associated with a risk to safety. Not recommended in patients with autoimmune diseases. Patients with rare hereditary problems of galactose intolerance, the LAPP lactase deficiency or glucose-galactose malabsorption should not take this medicine.
Fertility, pregnancy and lactation: Circadin use in pregnancy and in women intending to become pregnant isnot recommended and breast-feeding is not recommended in women receiving melatonin.
Driving: Circadin has moderate influence on the ability to drive and use machines.
Interactions: Fluvoxamine should be avoided. Caution should be used in patients on 5- or 8-methoxypsoralen (5- and 8-MOP), cimetidine and oestrogens. Cigarette smoking may decrease melatonin levels. CYP1A2 inhibitors such as quinolones may give rise to increased melatonin exposure. CYP1A2 inducers such as carbamazepine and rifampicin may give rise to reduced melatonin exposure. Alcohol should not be taken with Circadin. Sedative properties of benzodiazepines and non-benzodiazepine hypnotics may be enhanced.
Undesirable effects: In clinical trials the rate of patients with adverse events per 100 patient weeks was higher for Placebo than Circadin (5.743 placebo vs. 3.013 Circadin). There are no very common (≥1/10) or common (≥1/100 to <1/10) adverse reactions. Uncommon (≥1/1,000 to <1/100) adverse reactions include hypertension, chest pain, migraine, headache, irritability, abnormal dreams, nightmares, dermatitis, menopausal symptoms, abdominal pain, abnormal liver function test and asthenia. Rare (≥1/10,000 to <1/1,000) adverse reactions include loss of consciousness, angina, palpitations, depression, visual impairment, disorientation, vertigo, haematuria, leukopenia, thrombocytopenia and abnormal laboratory test. Prescribers should consult the full Summary of Product Characteristics for further information on adverse reactions.
Legal category: POM.
Pack size: Circadin 2mg, 30 tablets.
Marketing Authorisation number: EU/1/07/392/003.
Marketing Authorisation holder: RAD Neurim Pharmaceuticals EEC SARL, 4 rue de Marivaux, 75002 Paris, France.
Further information available from: Flynn Pharma Ltd. Hertlands House, Primett Road, Stevenage, Hertfordshire, SG1 3EE. Medical Information: Tel +44 1438 727822 or medinfo@flynnpharma.com
Date of last revision of PI: March 2019.

Adverse events should be reported to the Health Products Regulatory Authority (HPRA) using an Adverse Reaction Report Form obtained either from HPRA or electronically via the website at www.hpra.ie. Adverse reactions can also be reported to the HPRA by calling (01) 676 4971. Adverse events should also be reported to Flynn Pharma Ltd. Medical Information: Tel +44 1438 727822.

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