

Safeguarding public health
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MHRA

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 20 March 2013

EL (13)A/10

Our Ref: MDR 35-03/13

Dear Healthcare Professional,

RAD Neurim Pharmaceuticals EEC Limited

Circadin 2mg prolonged-release tablets **EU/1/07/392/003**
(Melatonin)

Flynn Pharma Limited, distributors of Circadin 2mg prolonged-release tablets, has informed us that there is an error in the patient information leaflet (PIL) supplied in batches of this product distributed since 11 February 2013.

The error concerns the dosage instructions given under heading 3, 'How to take Circadin', which state 'The recommended dose is one Circadin tablet (2mg) taken daily by mouth after food, 12 hours before bedtime.' The instructions should state 'The recommended dose is one Circadin tablet (2mg) taken daily by mouth after food, **1-2 hours before bedtime.**' The SPC is correct and an updated version of the PIL is presented on the Electronic Medicines Compendium. Health Care Professionals are asked to ensure that patients are made aware of the correct dosage instructions.

In order to avoid stock disruption, affected stock is not being recalled. We understand that distribution of affected stock will cease as soon as stock containing the corrected PIL is available.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Primary Care Trusts are asked to forward this to relevant clinics and to General Practitioners and Community Pharmacists for information.

Yours faithfully

Alison Bunce

Pharmaceutical Assessor, DMRC

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Regional Contacts for NHS Trusts and Provider Units
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