

**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 from an autoimmune disease (where the body is 'attacked' by its own immune system). No studies on the use of Circadin in people with auto-immune diseases have been performed; therefore, you should speak to your doctor before taking Circadin as its use is not recommended.
- Circadin can make you feel drowsy, you should be careful if the drowsiness affects you as it may impair your ability on tasks such as driving.
- Smoking may make Circadin less effective, because the components of tobacco smoke can increase the breakdown of melatonin by the liver.

**Children and adolescents**

Do not give this medicine to children between the ages of 0 to 18 years as it has not been tested and its effects are unknown.

**Other medicines and Circadin**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. These medicines include:

- Fluvoxamine (used for the treatment of depression and obsessive compulsive disorder),
- psoralens (used in the treatment of

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 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 Circadin**

If you forget to take your tablet, take another as soon as you remember, before going to sleep, 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 interrupted or ended early. The use of Circadin is not known to cause any withdrawal effects after treatment 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
- 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 disorder, inflammation of the stomach lining, eczema, skin rash, hand dermatitis, itchy rash, nail disorder, arthritis, muscle spasms, neck pain, night cramps, prolonged erection that might be painful, inflammation of the prostate gland, tiredness, pain, thirst, passing large volumes of urine, urinating during the night, increased liver enzymes, abnormal blood electrolytes and abnormal laboratory tests.

**Frequency not known:** (cannot be established from the available data) Hypersensitivity reaction, swelling of mouth or tongue, swelling of the skin and abnormal milk secretion.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

United Kingdom

Yellow Card Scheme  
Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

Ireland

HPRa Pharmacovigilance  
Earlsfort Terrace  
IRL - Dublin 2  
Tel: +353 1 6764971  
Fax: +353 1 6762517  
Website: [www.hpra.ie](http://www.hpra.ie)  
e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

Malta  
ADR Reporting  
The Medicines Authority  
Post-Licensing Directorate  
203 Level 3, Rue D'Argens  
GŻR-1368 Gżira  
Website:  
www.medicinesauthority.gov.mt  
e-mail:  
postlicensing.medicinesauthority@gov.mt

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Circadin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton (EXP). The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## 6. Contents of the pack and other information

### What Circadin contains

- The active substance is melatonin. Each prolonged-release tablet contains 2 mg 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 2 mg 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 and Manufacturer

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 - Indústria Farmacêutica S.A.  
Rua Consiglieri Pedroso, n.o 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>

#### België/Belgique/Belgien

Takeda Belgium  
Tél/Tel: +32 2 464 06 11  
Takeda-Belgium@takeda.com

#### България

RAD Neurim Pharmaceuticals EEC Limited  
Ten: +44 7563543352 (UK)  
e-mail: neurim@neurim.com

#### Česká republika

RAD Neurim Pharmaceuticals EEC Limited  
Tel: +44 7563543352 (UK)  
e-mail: neurim@neurim.com

#### Danmark

Takeda Pharma A/S  
Tlf: +45 46 77 11 11

#### Deutschland

Medice Arzneimittel Pütter GmbH & Co. KG  
Tel: +49 (0)2371 9370  
info@medice.de

#### Eesti

Takeda Pharma AS  
Tel: +372 6177669

#### Ελλάδα

TAKEDA ΕΜΑΣ Α.Ε.  
Τηλ: +30 210 6387800  
gr.info@takeda.com

#### España

EXELTIS HEALTHCARE, S.L.  
Tfn: +34 91 7711500

#### France

Biocodex  
Tél: +33 (0)1 41 24 30 00  
e-mail: webar@biocodex.fr

#### Hrvatska

RAD Neurim Pharmaceuticals EEC Limited  
Tel: +44 7563543352 (UK)  
e-mail: neurim@neurim.com

#### Ireland

Flynn Pharma Limited  
Tel: +44 (0) 1438 727822 (UK)  
medinfo@flynnpharma.com

#### Ísland

Vistor hf  
Sími: +354 535 7000

#### Italia

Fidia Farmaceutici S.p.A  
Tel: +39 049 8232355  
e-mail: info@fidiafarma.it

#### Κύπρος

RAD Neurim Pharmaceuticals EEC Limited  
Τηλ: +44 7563543352 (UK)  
e-mail: neurim@neurim.com

#### Latvija

Takeda Latvia SIA  
Tel: +371 67840082  
lv-info@takeda.com

#### Lietuva

Takeda, UAB  
Tel: +370 521 09 070  
lt-info@takeda.com

#### Luxembourg/Luxemburg

Takeda Belgium  
Tél/Tel: +32 2 464 06 11 (BE)  
Takeda-Belgium@takeda.com

#### Magyarország

RAD Neurim Pharmaceuticals EEC Limited  
Tel: +44 7563543352 (UK)  
e-mail: neurim@neurim.com

#### Malta

RAD Neurim Pharmaceuticals EEC Limited  
Tel: +44 7563543352 (UK)  
e-mail: neurim@neurim.com

#### Nederland

Takeda Nederland bv  
Tel: +31 23 566 8777  
nl.medical.info@takeda.com

#### Norge

Takeda AS  
Tlf: +47 6676 3030  
infororge@takeda.com

#### Österreich

SANOVA PHARMA GesmbH  
Tel: +43 (01) 80104-0  
e-mail: sanova.pharma@sanova.at

#### Polska

MEDICE Arzneimittel Pütter GmbH & Co. KG  
Tel.: + 48-(0)22 642 2673  
e-mail: office@medice.pl

#### Portugal

Italfarmaco, Produtos Farmacêuticos, Lda.  
Tel: +351 214 342 530  
e-mail: geral@itf-farma.pt

#### România

RAD Neurim Pharmaceuticals EEC Limited  
Tel: +44 7563543352 (UK)  
e-mail: neurim@neurim.com

#### Slovenija

RAD Neurim Pharmaceuticals EEC Limited  
Tel: +44 7563543352 (UK)  
e-mail: neurim@neurim.com

#### Slovenská republika

RAD Neurim Pharmaceuticals EEC Limited  
Tel: +44 7563543352 (UK)  
e-mail: neurim@neurim.com

#### Suomi/Finland

Takeda Oy  
Puh/Tel: +358 20 746 5000

#### Sverige

Takeda Pharma AB  
Tel: +46 8 731 28 00  
infosweden@takeda.com

#### United Kingdom

Flynn Pharma Limited  
Tel: +44 (0) 1438 727822  
medinfo@flynnpharma.com



# IBERFAR

INDÚSTRIA FARMACÊUTICA, S.A.

Artigo / Article:

FI CIRCADIN 2MG UK\_IR\_MT

Código IBF / IBF Code:

01041644-V2

Versão IBF / IBF Version:

V01

Gramagem / Total weight:

50 g/m<sup>2</sup>

Dimensões / Dimensions:

170 x 400 mm

Pré-dobrados (dimensões) / Pre-folded (dimensions):

38 x 170 mm

Braille:

Não aplicável / Not applicable

Pantone:



Black

Código Laetus / Laetus Pharmacode:



430

Desenrolamento / Unwinding direction:

Não aplicável / Not applicable

Preparado por / Prepared by:

Isabel Felício

Data / Date:

05/04/2017

IBERFAR, INDÚSTRIA FARMACÊUTICA, S. A.  
R. Consiglieri Pedroso, n.º 123, Queluz de Baixo  
2734-501 BARCARENA, Portugal  
T.+351 21 434 81 00 / F. +351 21 434 81 01  
www.iberfar.pt