

PATIENT INFORMATION LEAFLET**CIRCADIN 2 mg****SCHEDULING STATUS:**

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

CIRCADIN® 2 mg (prolonged-release tablet)

Please read all of this leaflet carefully before you start taking CIRCADIN 2 mg tablets.

- Please keep this leaflet. You may need to read it again.
- If you have further questions please ask your doctor or pharmacist.
- **CIRCADIN® 2 mg tablets** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT CIRCADIN® 2 mg CONTAINS:

Each tablet contains 2 mg melatonin as the active ingredient.

The product also contains the following inactive ingredients:

Ammonio methacrylate copolymer type B, (Eudragit RSPO), calcium hydrogen phosphate dihydrate, lactose monohydrate, magnesium stearate, silica colloidal anhydrous (Aerosil), talcum.

WHAT CIRCADIN® 2 mg IS USED FOR:

CIRCADIN® 2 mg is used for the treatment of sleeplessness characterised by poor quality of sleep in patients who are aged 55 years or over, for up to 3 weeks.

BEFORE TAKING CIRCADIN® 2 mg:**Do not take CIRCADIN® 2 mg:**

- *If you are allergic:* It is not recommended that you use CIRCADIN® 2 mg if you are allergic to any of the ingredients.

- *If you are pregnant or planning to become pregnant:* The effects of CIRCADIN® 2 mg on pregnant women or their unborn babies are not known. It is not recommended that you use CIRCADIN® 2 mg if you are pregnant.
- *If you are breast-feeding:* It is not recommended that you use CIRCADIN® 2 mg if you are breast feeding.
- *If you are using alcohol:* Alcohol should not be taken with CIRCADIN® 2 mg, because it reduces the effectiveness of CIRCADIN® 2 mg on sleep.

Take special care with CIRCADIN® 2 mg:

- CIRCADIN® 2 mg has minimal influence on the ability to drive and use machines. Nevertheless, you should avoid engaging in hazardous activities (such as driving or operating machinery) after taking CIRCADIN® 2 mg.
- If you suffer from a rare hereditary problems of galactose intolerance, the LAPP lactase deficiency or glucose-glucose malabsorption, inform your doctor before using the product.

If you are pregnant or breast feeding your baby while using CIRCADIN® 2 mg please consult your doctor, pharmacist or other health care professional for advice.

Taking CIRCADIN® 2 mg with other medicines:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Certain medicines can influence the blood levels of CIRCADIN® 2 mg if used simultaneously. Inform your doctor if you are taking any of the following medicines:

- Certain antidepressants such as fluvoxamine.
- 5 - or 8-methoxypsoralen (5 and 8-MOP), a medicine used to treat skin diseases.
- Certain medicines used to treat ulcers, such as cimetidine.
- Oestrogens (eg contraceptive or hormone replacement therapy).
- Certain antibiotics called quinolones and rifampicin.
- Certain anti-epileptic medicines such as carbamazepine.
- CIRCADIN 2 mg may increase the sedative properties of other sleeping tablets and hypnotics, such as zalepon, zolpidem and zopiclone.

HOW TO TAKE CIRCADIN® 2 mg:

Do not share medicines prescribed for you with any other person.

Always take CIRCADIN® 2 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

The dose is one tablet at night, after food, 1-2 hours before bedtime, for a maximum of 3 weeks.

You should swallow the tablet whole. Do not crush or cut the tablet.

If you forget to take a dose, take another as soon as you remember, before going to sleep, or wait and take your next dose at the normal time it is due. Do not take a double dose to make up for the dose that you missed.

If you have the impression that the effect of CIRCADIN® 2 mg is too strong or too weak, tell your doctor or pharmacist.

This product is for you. Please do not give it to anyone else, even if they have the same symptoms as you.

If you take more CIRCADIN® 2 mg than you should, you will feel drowsy.

In the event of an over-dosage, consult your doctor or pharmacist. If neither is available, *contact* the patient to the nearest hospital or poison control centre. Show the pack to the doctor.

POSSIBLE SIDE EFFECTS:

CIRCADIN® 2 mg can have side-effects. The following side-effects may occur:

- Irritability.
- Nervousness.
- Restlessness, sleeplessness.
- Abnormal dreams.
- Migraine.
- Restlessness associated with increased activity.
- Dizziness.
- Tiredness.

- Abdominal (stomach) pain.
- Constipation.
- Dry mouth.
- Changes in the composition of your blood which could cause yellowing of the skin or eyes.
- Excessive sweating.
- Feeling of weakness.
- Weight increase.

Other side-effects that occur less frequently are:

Shingles, blood disorders, altered mood, aggression, agitation, crying, early morning awakening, increased sex drive, memory impairment, disturbance in attention, poor quality sleep, visual impairment, blurred vision, watery eyes, dizziness when standing, hot flushes, upset stomach, vomiting, abnormal bowel sounds, wind, excess saliva production, bad breath, increased liver enzymes, eczema, skin rash, itchy rash, itching, dry skin, nail disorder, night sweats, muscle cramp, neck pain, increased duration of erection and tiredness.

Not all side-effects reported for CIRCADIN® 2 mg are included in this leaflet. Should your general health worsen while taking CIRCADIN® 2 mg, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF CIRCADIN® 2 mg:

Store at or below 25 °C. Protect from light. Keep in the carton until required for use.

Keep all medicines out of reach and sight of children.

Do not use the product after the expiry date which is stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

PRESENTATION OF CIRCADIN® 2 mg:

The tablets are packed in white opaque PVC/PVdC/ aluminium blisters. One blister strip containing 20, 21 or 30 tablets are packed in a cardboard carton.

IDENTIFICATION OF CIRCADIN® 2 mg:

White to off-white, round biconvex tablet with no imprint or break-line.

REGISTRATION NUMBER:

44/2.2/0001

THE NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER:

TAKEDA (Pty) Ltd

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