

# RESTIN™ melatonin

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using RESTIN melatonin?

RESTIN melatonin contains the active ingredient Melatonin. RESTIN melatonin is used to improve sleep quality and morning alertness in patients over 55 years of age diagnosed with primary insomnia with poor quality of sleep.

For more information, see Section [1. Why am I using RESTIN melatonin?](#) in the full CMI.

### 2. What should I know before I use RESTIN melatonin?

Do not use if you have ever had an allergic reaction to RESTIN melatonin or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use RESTIN melatonin ?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with RESTIN melatonin and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use RESTIN melatonin?

- Adults 55 years and over: Take one tablet after food, 1-2 hours before you go to bed.

More instructions can be found in Section [4. How do I use RESTIN melatonin?](#) in the full CMI.

### 5. What should I know while using RESTIN melatonin?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using RESTIN melatonin.</li><li>If you become pregnant while taking RESTIN melatonin, stop taking the tablets and tell your doctor immediately.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not take RESTIN melatonin to treat any other complaints unless your doctor tells you.</li><li>Do not give your medicine to anyone else, even if they have the same condition as you.</li><li>Do not take more than the recommended dose unless your doctor tells you to.</li><li>Do not drink alcohol before or after taking this medicine.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>This medicine rarely causes drowsiness, nevertheless it is not recommended to drive or operate machinery for 8 hours after you take it.</li><li>This medicine does not impair morning alertness, but if you suffer from drowsiness during the day you should consult your doctor.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>Do not drink alcohol before or after taking this medicine.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep your tablets in the blister pack until it is time to take them.</li><li>Keep RESTIN melatonin away from sunlight.</li><li>Keep RESTIN melatonin in a cool, dry place where the temperature says below 25°C.</li></ul>

For more information, see Section [5. What should I know while using RESTIN?](#) in the full CMI.

### 6. Are there any side effects?

This medicine has been shown to improve the sleep of most people aged over 55 years, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# RESTIN™ melatonin

Active ingredient(s): *Melatonin*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using RESTIN melatonin. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using RESTIN melatonin.**

Where to find information in this leaflet:

- [1. Why am I using RESTIN melatonin?](#)
- [2. What should I know before I use RESTIN melatonin?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use RESTIN melatonin?](#)
- [5. What should I know while using RESTIN melatonin?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using RESTIN melatonin?

**RESTIN melatonin contains the active ingredient melatonin.** The active substance of RESTIN melatonin, melatonin, belongs to a group of naturally occurring hormones produced by the body.

Melatonin works by controlling the circadian rhythms and increasing the propensity to sleep.

**RESTIN melatonin is used to improve sleep quality and morning alertness in patients over 55 years of age diagnosed with primary insomnia with poor quality of sleep.**

### 2. What should I know before I use RESTIN melatonin?

#### Warnings

**Do not use RESTIN melatonin if:**

- you are allergic to melatonin, or any of the ingredients listed at the end of this leaflet.  
Always check the ingredients to make sure you can use this medicine.
- you have been drinking alcohol or intend to drink alcohol or believe that you may have alcohol in your blood stream.
- you are pregnant or breast-feeding. RESTIN melatonin has not been studied in pregnant or breast-feeding women.

**Check with your doctor or pharmacist if you:**

- have or have had the following medical conditions:
- suffer from liver problems
- suffer from kidney problems
- suffer from an autoimmune disease

- have a rare hereditary problem of galactose intolerance, the LAPP lactase deficiency or glucose-galactose malabsorption
- take any medicines for any other condition
- Do not give RESTIN melatonin to a child or adolescent. There is no experience with its use in children or adolescents under 18 years old.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Do not take RESTIN melatonin if you are pregnant or breast-feeding. RESTIN melatonin has not been studied in pregnant or breast-feeding women.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with RESTIN melatonin and affect how it works. These include:**

- Hypnotics and tranquilisers (e.g. benzodiazepine)
- Fluvoxamine, thioridazine and imipramine (used to treat depression or psychiatric problems).
- oestrogen (contraceptives or hormone replacement therapy).
- Cimetidine and psoralens (used to treat skin problems e.g. psoriasis).
- alcohol.
- caffeine

The effect of adding RESTIN melatonin to other medicines used to treat insomnia has not been examined. It is not known if RESTIN melatonin will increase or decrease the effects of other treatments for insomnia.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect RESTIN melatonin.**

### 4. How do I use RESTIN melatonin?

#### How much to take / use

- The standard dose of RESTIN melatonin is one tablet once a day. There is no evidence that taking more than the recommended dose will increase the effect of RESTIN melatonin.
- Swallow your tablet whole with a full glass of water.
- Do not crush, chew or divide your tablet.**

- Each RESTIN melatonin tablet has been specially designed to release the right dose of medicine while you sleep. If you crush, chew or divide the tablet they will not work properly.
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.

### When to take RESTIN melatonin

- RESTIN melatonin should be taken after food, 1-2 hours before you go to bed.

### If you forget to use RESTIN melatonin

RESTIN melatonin should be used regularly at the same time each day. If you miss your dose at the usual time, take another as soon as you remember, before going to bed or wait until it is time for your next dose.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

**Do not take a double dose to make up for the dose you missed.**

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

### If you take too much RESTIN melatonin

If you think that you have taken too much RESTIN melatonin, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26)
- contact your doctor
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using RESTIN melatonin?

### Things you should do

#### Call your doctor straight away if you:

- Become pregnant while taking RESTIN melatonin, stop taking the tablets and tell your doctor immediately.
- Remind any doctor, dentist, pharmacist that you are using RESTIN melatonin.

#### Follow these principles of good sleep hygiene:

- Go to bed and arise at the same time daily.
- Engage in relaxing activities before bedtime.
- Exercise regularly but not in the late evening.
- Avoid eating meals or large snacks just before bedtime.
- Eliminate daytime naps.
- Avoid caffeine-containing drinks after midday.
- Avoid alcohol or the use of nicotine late in the evening.
- Minimise external disruption (e.g., light and noise).

- If you are unable to sleep, do not become anxious; leave the bedroom and participate in relaxing activities such as reading or listening to music until you are tired.

### Things you should not do

- Do not take RESTIN melatonin to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not take more than the recommended dose unless your doctor tells you to.
- Do not drink alcohol before or after taking this medicine.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how RESTIN melatonin affects you.**

RESTIN melatonin rarely causes drowsiness, nevertheless it is not recommended to drive or operate machinery for 8 hours after you take it. RESTIN melatonin does not impair morning alertness, but if you suffer from drowsiness during the day you should consult your doctor.

### Drinking alcohol

**Tell your doctor or pharmacist if you drink alcohol.**

Do not drink alcohol before or after taking this medicine.

### Looking after your medicine

- Keep RESTIN melatonin away from sunlight.
- Keep RESTIN melatonin in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<p><b>Psychiatric Disorders</b></p> <ul style="list-style-type: none"> <li>Irritability, nervousness, restlessness, insomnia, abnormal dreams, anxiety, nightmares</li> </ul> <p><b>Nervous System Disorders</b></p> <ul style="list-style-type: none"> <li>Migraine, lethargy, psychomotor hyperactivity (restlessness associated with increased activity), dizziness, somnolence (tiredness), headache</li> </ul> <p><b>Vascular Disorders</b></p> <ul style="list-style-type: none"> <li>High blood pressure</li> </ul> <p><b>Gastrointestinal Disorders</b></p> <ul style="list-style-type: none"> <li>Abdominal pain (upper), indigestion, mouth ulceration, dry mouth, nausea</li> </ul> <p><b>Hepatobiliary Disorders</b></p> <ul style="list-style-type: none"> <li>Hyperbilirubinaemia (changes in the composition of your blood which could cause yellowing of the skin or eyes (jaundice))</li> </ul> <p><b>Skin and Subcutaneous Tissue Disorders</b></p> <ul style="list-style-type: none"> <li>Inflammation of the skin (dermatitis), night sweats, pruritis (itching), rash, dry skin</li> </ul> <p><b>Musculoskeletal and Connective Tissue Disorders</b></p> <ul style="list-style-type: none"> <li>Pain in extremities</li> </ul> <p><b>Reproductive System and Breast Disorders</b></p> <ul style="list-style-type: none"> <li>Menopausal symptoms</li> </ul> <p><b>General Disorders and Administration Site Conditions</b></p> <ul style="list-style-type: none"> <li>Asthenia (feeling of weakness), chest pain</li> </ul> <p><b>Renal and Urinary Disorders</b></p> <ul style="list-style-type: none"> <li>Excretion of glucose in urine, excess proteins in the urine</li> </ul> <p><b>Investigations</b></p> <ul style="list-style-type: none"> <li>Liver Function Test abnormal, weight increase</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Rare side effects

Serious side effects	What to do

<p><b>Infections and Infestations</b></p> <ul style="list-style-type: none"> <li>Shingles</li> </ul> <p><b>Blood and Lymphatic System Disorders</b></p> <ul style="list-style-type: none"> <li>Reduced number of white blood cells in the blood, decreased number of platelets in the blood</li> </ul> <p><b>Cardiac Disorders</b></p> <ul style="list-style-type: none"> <li>Severe chest pain due to angina, feeling your heartbeat (palpitations)</li> </ul> <p><b>Immune System Disorders</b></p> <ul style="list-style-type: none"> <li>Hypersensitivity reaction</li> </ul> <p><b>Metabolism and Nutrition Disorders</b></p> <ul style="list-style-type: none"> <li>High level of fatty molecules in the blood, low serum calcium levels in the blood, low sodium levels in the blood</li> </ul> <p><b>Psychiatric Disorders</b></p> <ul style="list-style-type: none"> <li>Altered mood, aggression, agitation, crying, stress symptoms, disorientation, early morning awakening, increased sex drive, depressed mood, depression</li> </ul> <p><b>Nervous System Disorders</b></p> <ul style="list-style-type: none"> <li>Loss of consciousness or fainting, memory impairment, disturbance in attention, dreamy state, restless legs syndrome, poor quality sleep, 'pins and needles' feeling (paresthesia)</li> </ul> <p><b>Eye Disorders</b></p> <ul style="list-style-type: none"> <li>Reduced visual acuity (visual impairment), blurred vision, watery eyes</li> </ul> <p><b>Ear and Labyrinth Disorders</b></p> <ul style="list-style-type: none"> <li>Dizziness when standing or sitting, vertigo</li> </ul> <p><b>Vascular Disorders</b></p> <ul style="list-style-type: none"> <li>Hot flushes</li> </ul> <p><b>Gastrointestinal Disorders</b></p> <ul style="list-style-type: none"> <li>Gastro-oesophageal reflux, gastrointestinal disorder, blistering in the mouth, tongue ulceration, gastrointestinal upset, vomiting, abnormal bowel sounds, flatulence (wind), salivary hypersecretion (excess saliva production), halitosis (bad breath), abdominal discomfort, gastric disorder, inflammation of the stomach lining</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>
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<p><b>Skin and Subcutaneous Tissue Disorders</b></p> <ul style="list-style-type: none"> <li>Eczema, erythema (skin rash), hand dermatitis, psoriasis, pruritic rash (itchy rash), nail disorder</li> </ul> <p><b>Musculoskeletal and Connective Tissue Disorders</b></p> <ul style="list-style-type: none"> <li>Arthritis, muscle spasms, neck pain, night cramps</li> </ul> <p><b>Reproductive System and Breast Disorders</b></p> <ul style="list-style-type: none"> <li>Increased duration of erection, inflammation of the prostate gland</li> </ul> <p><b>General Disorders and Administration Site Conditions</b></p> <ul style="list-style-type: none"> <li>Tiredness, pain, thirst</li> </ul> <p><b>Renal and Urinary Disorders</b></p> <ul style="list-style-type: none"> <li>Passing large volumes of urine, presence of red cells in the urine, urination during the night</li> </ul> <p><b>Investigations</b></p> <ul style="list-style-type: none"> <li>Increased liver enzymes, abnormal blood electrolytes and abnormal tests</li> </ul>	
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	Colloidal anhydrous silica, Purified talc, Magnesium stearate
<b>Potential allergens</b>	Lactose

**Do not take this medicine if you are allergic to any of these ingredients.**

### What RESTIN melatonin looks like

RESTIN melatonin tablets are white to off-white round biconvex shaped tablets, plain on both sides. (AUST R 440550).

Restin is available as packs of 7, 15, 21 and 30 tablets as Pharmacist Only Medicine (Schedule 3). Not all pack sizes may be marketed.

Restin is available as a pack of 60 tablets as Prescription Only Medicine (Schedule 4).

### Who distributes RESTIN melatonin

Nova Pharmaceuticals Australasia Pty Ltd  
Suite 305, 10 Norbrik Drive,  
Bella Vista NSW 2153  
novapharm.com.au

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is available from the pharmacist.

### What RESTIN melatonin contains

<b>Active ingredient (main ingredient)</b>	Melatonin 2mg
<b>Other ingredients (inactive ingredients)</b>	Ammonio methacrylate copolymer type B, Calcium hydrogen phosphate, Lactose,