

# Melatonin MR-TEVA<sup>®</sup>

## 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 Melatonin MR-TEVA?

Melatonin MR-TEVA contains the active ingredient melatonin. Melatonin MR-TEVA is used to improve sleep quality and morning alertness in patients over 55 years of age with primary insomnia with poor quality of sleep. For more information, see Section [1. Why am I using Melatonin MR-TEVA?](#) in the full CMI.

### 2. What should I know before I use Melatonin MR-TEVA?

Do not use if you have ever had an allergic reaction to Melatonin MR-TEVA or any of the ingredients listed at the end of the CMI. Talk to your doctor or pharmacist 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 Melatonin MR-TEVA?](#) in the full CMI.

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

Some medicines may interfere with Melatonin MR-TEVA 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 Melatonin MR-TEVA?

- Take Melatonin MR-TEVA only when prescribed by your doctor or pharmacist. Follow the instructions provided with the medicine.
- The standard dose of Melatonin MR-TEVA is one tablet once a day. Do not exceed the recommended dosage.

More instructions can be found in Section [4. How do I use Melatonin MR-TEVA?](#) in the full CMI.

### 5. What should I know while using Melatonin MR-TEVA?

<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 Melatonin MR-TEVA.</li><li>• If you become pregnant or start breastfeeding while taking Melatonin MR-TEVA, stop taking the tablets and tell your doctor or pharmacist immediately.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give Melatonin MR-TEVA 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 or pharmacist tells you to.</li><li>• Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• It is not recommended to drive or operate machinery for 8 hours after you take it.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Do not take Melatonin MR-TEVA if you have been drinking alcohol or intend to drink alcohol or believe that you may have alcohol, in your blood stream.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 25°C</li><li>• Keep your tablets in the blister pack until it is time to take them.</li></ul>

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

### 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 Section [6. Are there any side effects?](#) in the full CMI for detailed information on side effects and, if you need to, ask your doctor or pharmacist if you have any further questions.

# Melatonin MR-TEVA<sup>®</sup> (MELATONIN) MODIFIED RELEASE TABLETS

Active ingredient: Melatonin

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Melatonin MR-TEVA. **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 Melatonin MR-TEVA.**

**Where to find information in this leaflet:**

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

### 1. Why am I using Melatonin MR-TEVA?

**Melatonin MR-TEVA contains the active ingredient melatonin.** Melatonin MR-TEVA is (not of plant or animal origin), belongs to a group of naturally occurring hormones produced in the body.

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

**Melatonin MR-TEVA is used to improve sleep quality and morning alertness in patients over 55 years of age with primary insomnia with poor quality of sleep.**

### 2. What should I know before I use Melatonin MR-TEVA?

#### Warnings

**Do not use Melatonin MR-TEVA 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.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, or rash, itching or hives on the skin.

- Do not take Melatonin MR-TEVA if you have been drinking alcohol or intend to drink alcohol or believe that you may have alcohol, in your blood stream.
- Do not take Melatonin MR-TEVA if you are pregnant or breast-feeding. Melatonin MR-TEVA has not been studied in pregnant or breast-feeding women.

**Do not take it if the packaging is torn or shows signs of tampering.**

If you are not sure whether you should start taking Melatonin MR-TEVA talk to your doctor.

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

- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- take any medicines for any other condition
- you have, or have had the following medical conditions:
  - suffer from liver problems
  - suffer from kidney problems
  - If you suffer from an autoimmune disease
  - have a rare hereditary problem of galactose intolerance, the LAPP lactase deficiency or glucose-galactose malabsorption

Do not give Melatonin MR-TEVA 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

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

### 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 Melatonin MR-TEVA 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 Melatonin MR-TEVA to other medicines used to treat insomnia has not been examined. It is not known if Melatonin MR-TEVA 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 Melatonin MR-TEVA.** They will have more information on medicines to be careful with or avoid while taking Melatonin MR-TEVA.

## 4. How do I use Melatonin MR-TEVA?

### How much to take

Take Melatonin MR-TEVA only when prescribed by your doctor or pharmacist.

- The standard dose of Melatonin MR-TEVA is one tablet once a day.
- There is no evidence that taking more than the recommended dose will increase the effect of Melatonin MR-TEVA.
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.

### How to take Melatonin MR-TEVA

- Swallow your tablet whole with a full glass of water.
- **Do not crush, chew or divide your tablet.**
- Each Melatonin MR-TEVA 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 all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.**
- If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

### When to take Melatonin MR-TEVA

- Melatonin MR-TEVA should be taken with or soon after food (or with a snack), 1-2 hours before you go to bed.

### How long to take Melatonin MR-TEVA

- It is important that you continue taking Melatonin MR-TEVA for as long as your doctor or pharmacist prescribes.
- Do not take for longer than 3 weeks unless advised by a doctor.

### If you forget to take Melatonin MR-TEVA

- If you forget to take your tablet, take another as soon as you remember, before going to bed or wait until it is time for your next dose.
- **Do not take a double dose to make up for a forgotten dose.**
- **If you are not sure what to do, talk to your doctor or pharmacist.**
- If you have trouble remembering to take your Melatonin MR-TEVA, ask your pharmacist for some hints.

## If you use too much Melatonin MR-TEVA

If you think that you have used too much Melatonin MR-TEVA, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre  
**(In Australia by calling 13 11 26 and in New Zealand 0800 POISON [0800 764 766]),** or
- contact your doctor or pharmacist, or
- 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 Melatonin MR-TEVA?

### Things you should do

- If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Melatonin MR-TEVA.
- Remind any doctor, dentist or pharmacist you visit that you are using Melatonin MR-TEVA.
- If you become pregnant while taking Melatonin MR-TEVA, stop taking the tablets and tell your doctor or pharmacist immediately.
- 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 give Melatonin MR-TEVA to anyone else, even if they have the same condition as you.**
- **Do not take more than the recommended dose unless your doctor or pharmacist tells you to.**
- **Do not use this medicine to treat any other complaints unless your doctor or pharmacist 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 Melatonin MR-TEVA affects you.**

Melatonin MR-TEVA rarely causes drowsiness, nevertheless it is not recommended to drive or operate machinery for 8 hours after you take it. Melatonin MR-TEVA does not impair morning alertness, but if you suffer

from drowsiness during the day you should consult your doctor or pharmacist.

### 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 your tablets in the blister pack until it is time to take them.**
- If you take the tablets out of the blister pack they may not keep well.

Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 25°C; 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.

A locked cupboard at least one- and-a-half metres above the ground is a good place to store medicines.

#### When to discard your medicine (as relevant)

If your doctor or pharmacist tells you to stop taking the tablets or the tablets have passed their expiry date.

#### 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.

#### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• Back pain, pain in joints, swelling of joints (arthritis), pain in the extremities, neck pain, muscle spasms, feeling tired, night cramps</li> <li>• Diarrhea, constipation, nausea, vomiting, abdominal pain, indigestion, dry mouth, mouth ulceration or blistering, tongue ulceration, weight increase, abnormal bowel sounds, flatulence (wind), excess saliva production, bad breath, abdominal discomfort, gastro-oesophageal reflux, inflammation of stomach lining, gastrointestinal disorder,</li> </ul>	<p><b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b></p>

Less serious side effects	What to do
<p>gastrointestinal upset, gastric disorder</p> <ul style="list-style-type: none"> <li>• Urinary tract infection</li> <li>• Excessive thirst, passing large volumes of urine, presence of red blood cells in the urine, urination during the night, Excretion of glucose in urine, excess proteins in urine</li> <li>• Cough or respiratory tract infections, cold</li> <li>• Irritability, nervousness, restlessness, psychomotor hyperactivity (restlessness associated with increased activity), insomnia, abnormal dreams, nightmares, anxiety, depression, lethargy, altered mood, aggression, increased sex drive, agitation, crying, stress symptoms, early morning awakening, dreamy state, restless legs syndrome, poor quality sleep</li> <li>• Headache, migraine, weakness, dizziness, night sweats, vertigo</li> <li>• Watery eyes</li> <li>• Itching, itchy rash, inflammation of skin, rash, dry skin, eczema, psoriasis, nail disorder</li> <li>• Increased blood pressure</li> <li>• Menopausal symptoms, hot flushes, increased duration of erection, inflammation of the prostate gland</li> <li>• Increased liver enzymes or abnormal liver function, hyperbilirubinaemia (changes in the composition of your blood which could cause yellowing of the skin or eyes (jaundice))</li> <li>• High level of fatty molecules in the blood, low serum calcium levels in the blood, low sodium levels in the blood, abnormal blood electrolytes, abnormal laboratory tests</li> </ul>	

#### Serious side effects

Serious side effects	What to do
<p><b>bleeding-related:</b></p> <ul style="list-style-type: none"> <li>• Heart palpitations, tightness or severe chest pain spreading to arms, jaw, shoulder or back, dizziness when standing or sitting</li> <li>• Reduced visual acuity (visual impairment), blurred vision</li> </ul>	<p><b>Call your doctor or pharmacist straight away, or go straight to the Emergency Department at</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>Loss of consciousness or fainting, memory impairment, disturbance in attention, disorientation, 'pins and needles' feeling (paresthesia)</li> <li>Leukopenia (decreased white blood cells), thrombocytopenia (decrease in platelets)</li> <li>Shingles</li> </ul>	<p><b>your nearest hospital if you notice any of these serious side effects.</b></p>

**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.

## 7. Product details

This medicine is available over-the-counter without a doctor's prescription.

### What Melatonin MR-TEVA contains

<b>Active ingredient (main ingredient)</b>	2 mg melatonin
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>Ammonio methacrylate copolymer type B,</li> <li>calcium hydrogen phosphate dihydrate,</li> <li>lactose monohydrate,</li> <li>colloidal anhydrous silica,</li> <li>purified talc</li> <li>magnesium stearate.</li> </ul>
<b>Potential allergens</b>	Lactose monohydrate

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

### What Melatonin MR-TEVA looks like

Melatonin MR-TEVA 2 mg tablets are white to off-white oval bi-convex shaped tablets, with A6 on one side.

Melatonin MR-TEVA tablets are available in a 7, 15, 21, 30 and 60 tablet pack\*.

\*some pack sizes are not marketed and the 60 tablet pack is only available with a doctor's prescription.

### Who distributes Melatonin MR-TEVA

Teva Pharma Australia Pty Ltd

Level 1, 37 Epping Road

Macquarie Park NSW 2113

Australia