

MELOTIN MR

Melatonin 2 mg modified release tablet

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about melatonin. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking melatonin against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What this medicine is used for

Melatonin is used to improve sleep quality and morning alertness in patients over 55 years of age with poor quality of sleep.

Melatonin belongs to a group of naturally occurring hormones produced in the body.

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is only available with a doctor's prescription.

This medicine is not addictive.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- melatonin
- any of the ingredients listed at the end of this leaflet.

Some of the 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
- rash, itching or hives on the skin.

Do not take melatonin if you have been drinking alcohol, intend to drink alcohol or believe that you may have alcohol in your blood stream.

Do not take melatonin if you are pregnant or breast-feeding.

This medicine has not been studied in pregnant or breast-feeding women.

Do not take melatonin after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking melatonin, talk to your doctor.

Before you start to take it

Tell your doctor if you have any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver problems
- kidney problems
- an autoimmune disease
- a rare hereditary problem of galactose intolerance, LAPP lactase deficiency or glucose-galactose malabsorption
- if you smoke cigarettes

If you have not told your doctor about any of the above, tell them before you take melatonin.

Taking other medicines

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

Some medicines and melatonin may interfere with each other. These include:

- hypnotics or tranquilisers (e.g. benzodiazepines)
- certain medicine used to treat mood disorders (e.g. fluvoxamine, thioridazine and imipramine)
- contraceptives or hormone replacement therapy containing oestrogen
- quinolones and rifampicin, used to treat infections

- carbamazepine, used to treat epilepsy
- cimetidine
- psoralens used to treat skin problems (e.g. psoriasis)
- alcohol
- caffeine

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

These medicines may be affected by melatonin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking melatonin.

How to take this medicine

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.

How much to take

The usual dose of melatonin is one tablet once a day.

There is no evidence that taking more than the recommended dose will increase the effect of melatonin.

How to take it

Swallow the tablet whole with a glass of water.

Do not crush, chew or divide your tablet.

Each 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

When to take it

Take your medicine at about the same time each day, about 1-2 hours before you go to bed.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Melatonin should be taken with food.

How long to take it

Continue taking melatonin for as long as your doctor tells you.

This medicine may be continued for up to thirteen weeks.

If you forget to take it

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.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, talk to your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much melatonin. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using this medicine

Things you must do

If you are about to be started on any new medicine, remind your

doctor and pharmacist that you are taking melatonin.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking melatonin, stop taking the tablets and tell your doctor immediately.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give this 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.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel

well while you are taking melatonin.

Melatonin helps most people with insomnia, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- gastrointestinal upset e.g. reflux, vomiting, abnormal bowel sounds, flatulence (wind), abdominal discomfort, upper abdominal pain or indigestion
- skin problems e.g. eczema, hand dermatitis, psoriasis, rash, itchy rash, dry skin
- weight increase
- irritability, agitation or restlessness
- anxiety or nervousness
- insomnia, abnormal dreams or early morning awakening
- increased sex drive
- migraine
- visual impairment, blurred vision or watery eyes
- dizziness when standing or sitting
- lethargy or tiredness
- nail disorder
- night sweats or night cramps
- dry mouth
- halitosis (bad breath)
- asthenia (feeling of weakness)
- muscle spasms
- salivary hypersecretion (excess saliva production)

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- shingles
- ‘pins and needles’ feeling (paresthesia)
- psychomotor hyperactivity (restlessness associated with increased activity)
- dizziness or somnolence (tiredness)
- high blood pressure
- mouth or tongue ulcers
- pain in extremities or neck pain
- altered mood or aggression
- crying or stress symptoms
- disorientation, disturbance in attention or dreamy state
- menopausal symptoms or hot flushes
- depression
- memory impairment
- restless legs syndrome
- vertigo
- inflammation of the stomach lining
- arthritis
- increased duration of erection
- inflammation of the prostate gland
- thirst, passing large volumes of urine or urination during the night

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- severe chest pain due to angina
- feeling your heartbeat (palpitations)
- hyperbilirubinaemia (changes in the composition of your blood which could cause yellowing of the skin or eyes (jaundice))
- loss of consciousness or fainting

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Some side effects can only be found when your doctor does blood or urine tests from time to time to check your progress. This includes:

- reduced number of white blood cells or platelets
- high level of fatty molecules
- presence of red blood cells in the urine
- excretion of glucose in urine
- excess proteins in the urine
- increased liver enzymes
- low levels of calcium or sodium in the blood
- abnormal blood electrolytes

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

Storage and Disposal

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C. Keep it away from sunlight.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking the tablets or the expiry date has passed, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

White to off-white round bi-convex shaped tablets. AUST R 250295.

Ingredients

Each tablet contains 2 mg melatonin as the active ingredient

It also contains the following:

- ammonio methacrylate copolymer type B
- calcium hydrogen phosphate dihydrate
- lactose monohydrate
- colloidal anhydrous silica
- purified talc
- magnesium stearate

Sponsor

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