National Custom Compounding
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MELATONIN

Consumer Medicine Information

What is in this leaflet

This leaflet contains answers to some common questions about MELATONIN.

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 MELATONIN 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.

The active substance of MELATONIN, melatonin, 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.

Your doctor, however, may prescribe MELATONIN for another purpose.

Ask your doctor or pharmacist if you have any questions about why it has been prescribed for you.

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

Melatonin is not addictive.

Before you take MELATONIN

When you must not take it

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 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 if you are pregnant or breast-feeding. MELATONIN has not been studied in pregnant or breast-feeding women.

Do not take it after the expiry date printed on the pack.

If you take it after the expiry date has passed, it may not work as well. The expiry date refers to the last day of the month.

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:

1. you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

2. you are pregnant or plan to become pregnant

3. you are breast-feeding or planning to breast-feeding

4. 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 problems of galactose intolerance, the LAPP lactase deficiency or glucose-galactose malabsorption

Do not give MELATONIN to a child or adolescent. There is no experience with its use in children or adolescents under 18 years old.

If you have not told your doctor about any of the above, tell him before you use MELATONIN.

Taking other medicines

Tell your doctor 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 may affect the way other medicines work.

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

- hypnotics and tranquilisers (e.g. benzodiazepines),
- 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 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.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking MELATONIN.

How to take MELATONIN

How much to take

Take MELATONIN only when prescribed by your doctor.

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

How to take it

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the container, ask your doctor or pharmacist for help.

When to take it

After food, 1-2 hours before you go to bed.

How long to take it

It is important that you continue taking MELATONIN for as long as your doctor prescribes. There is insufficient information on whether MELATONIN will continue to work effectively if taken for more than 3 weeks.

If you forget to take it

If you forget to take your melatonin, take some 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, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (In Australia 13 11 26 and in New Zealand 0800 764 766), or go to accident and emergency at your 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.

While you are using MELATONIN

Things you must do

If you are about to be started on any new medicine tell 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 become pregnant while taking MELATONIN, stop taking it and tell your doctor immediately.

Things you must not do

Do not give MELATONIN 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 use this medicine to treat any other complaints unless your doctor tells you to.

Do not drink alcohol before or after taking this medicine

Things to be careful of

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 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.

Tell your doctor if you notice any of the following and they worry you.

These are considered to be uncommon side effect(i.e., likely to occur in fewer than 1 in 100 patients):

Irritability, nervousness, restlessness insomnia, abnormal dreams, migraine, psychomotor hyperactivity (restlessness associated with increased activity), dizziness, somnolence (tiredness), abdominal pain, constipation, dry mouth,

hyperbilirubinaemia (changes in the composition of your blood which could cause yellowing of the skin or eyes also known as jaundice), hyperhidrosis (excessive sweating), asthenia (feeling of weakness) and weight increase

The following events are considered to be rare (i.e., likely to occur in fewer than 1 in 1,000 patients):

Herpes Zoster (shingles), leukopenia, thrombocytopenia, hypertriglyceridaemia, altered mood, aggression, agitation, crying, early morning awakening, increased libido (increased sex drive), memory impairment, disturbance in attention, poor quality sleep, reduced visual acuity (visual impairment), blurred vision, increased lacrimation (watery eyes), positional vertigo (dizziness when standing), hot flushes, gastrointestinal upset, vomiting, abnormal bowel sounds, flatulence (wind), salivary hypersecretion (excess saliva production), halitosis (bad breath), abnormal liver function test (increased liver enzymes), eczema, erythema (skin rash), pruritic rash (itchy rash), pruritus (itching), dry skin, nail disorder, night sweats, muscle cramp, neck pain, priapism (increased duration of erection) and fatigue (tiredness).

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects

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

MELATONIN is not addictive.

After using MELATONIN

Storage

Keep MELATONIN away from sunlight.

Keep the medicine in a cool dry place where the temperature stays below 25°C.

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

Do not leave it in the car. Heat and damp 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 melatonin or it has passed their expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.