MELATONIN-LINK

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.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using MELATONIN-LINK?

MELATONIN-LINK contains the active ingredient melatonin. MELATONIN-LINK is used to treat adults with jet lag and sleep disorders in children with neurodevelopmental disorders.

For more information, see Section 1. Why am I using MELATONIN-LINK? in the full CMI.

2. What should I know before I use MELATONIN-LINK?

Do not use if you have ever had an allergic reaction to MELATONIN-LINK 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 MELATONIN-LINK? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MELATONIN-LINK 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-LINK?

- The standard starting dose is 2 mg once daily, before bed or preferred sleep time. In some cases, your doctor may increase your dose.
- MELATONIN-LINK should be taken on an empty stomach.

More instructions can be found in Section 4. How do I use MELATONIN-LINK? in the full CMI.

5. What should I know while using MELATONIN-LINK?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using MELATONIN-LINK. • If you become pregnant while taking MELATONIN-LINK, stop taking the medication and tell your doctor immediately.
Things you should not do	• Do not give MELATONIN-LINK 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 while taking MELATONIN-LINK
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how MELATONIN-LINK affects you. MELATONIN-LINK causes drowsiness, which may continue into the daytime.
Looking after your medicine	• Store below 25°C • Store MELATONIN-LINK in original packaging to protect from light. • Discard oral solution 2 months after opening.

For more information, see Section 5. What should I know while using MELATONIN-LINK? in the full CMI.

6. Are there any side effects?

The most common side effects are sleepiness, headache, dizziness, nausea, stomach cramps and hyperactivity. Tell your doctor or pharmacist immediately, if you notice any of the following side effects: signs of an allergic reaction, seizures, tightness in chest, fast or irregular heartbeat, suicide attempt or suicidal thoughts.

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.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

MELATONIN-LINK

Active ingredient(s): melatonin

Strength and dose form: 1 mg/mL oral solution
2 mg oral capsules
3 mg oral capsules
5 mg oral capsules

Consumer Medicine Information (CMI)

This leaflet provides important information about using MELATONIN-LINK. **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-LINK.**

Where to find information in this leaflet:

1. Why am I using MELATONIN-LINK?
2. What should I know before I use MELATONIN-LINK?
3. What if I am taking other medicines?
4. How do I use MELATONIN-LINK?
5. What should I know while using MELATONIN-LINK?
6. Are there any side effects?
7. Product details

1. Why am I using MELATONIN-LINK?

MELATONIN-LINK contains the active ingredient melatonin. Melatonin is naturally occurring hormone produced in the body. It is one of the main hormones that helps you to sleep.

MELATONIN-LINK is used for the treatment of a number of conditions.

- **Jet lag** in adults 18 years and older.
- **Sleep Disorders in children and adolescents** aged 6 to 18 years with neurodevelopmental disorders including autism spectrum disorder (ASD) and attention deficit hyperactivity disorder (ADHD)

2. What should I know before I use MELATONIN-LINK?

Warnings

Do not use MELATONIN-LINK 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.

Check with your doctor if you:

- have or had the following medical conditions:
  - an autoimmune disease
  - a seizure disorder such as epilepsy
  - problems with your liver
  - problems with your kidneys
- take any medicines for any other condition.

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 if you are pregnant or intend to become pregnant.

Melatonin is not recommended if you or your child are pregnant. Melatonin crosses the placenta and there is insufficient information on the risk this may pose to the unborn child.

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

Melatonin is not recommended if you or your child are breastfeeding. Melatonin passes into human milk, and the risk to the breast-fed child cannot be excluded.

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-LINK and affect how it works.

These include:

- hypnotics (such as benzodiazepines, zolpidem and zopiclone)
- fluvoxamine, thioridazine and imipramine (used to treat depression or psychiatric conditions)
- oestrogens (contraceptives or hormone replacement therapies)
- cimetidine (used to treat reflux and stomach ulcers)
- psoralens (used to treat skin conditions such as psoriasis)
- antibiotics such as ciprofloxacin, moxifloxacin and norfloxacin (known as quinolones) and rifampicin
- carbamazepine (used to treat epilepsy).
- warfarin (anticoagulant)

- alcohol

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-LINK.

4. How do I use MELATONIN-LINK?

How much to take

Adults

- For the treatment of **jet lag**:
    - The standard starting dose is 2 mg once daily.
    - Your doctor may increase your dose up to 5 mg once daily.

Children and adolescents

- The standard starting dose is 2 mg once daily.
- Your doctor may increase your dose up to 5 mg once daily.

When to take MELATONIN-LINK

Adults

- For the treatment of **jet lag**:
    - Take the required dose at the preferred local sleep time of your travel destination.
    - Only use MELATONIN-LINK for a short period of time (no more than 5 days in a row).
    - Avoid taking MELATONIN-LINK before 8pm or after 4am. This may make the medicine less effective.

Children and adolescents

- For treatment of sleep disorders with **neurodevelopmental disorders:**
    - Take the required dose 30 minutes to 1 hour before bed.
    - Continue using MELATONIN-LINK only as long as the doctor recommends.

How to take the MELATONIN-LINK capsules

MELATONIN-LINK should be taken on an empty stomach, at least 1 hour before and at least 1 hour after a meal. The capsules should be swallowed whole with a glass of water or juice.

How to take the MELATONIN-LINK oral solution

MELATONIN-LINK should be taken on an empty stomach at least 1 hour before and at least 1 hour after a meal.

The oral solution pack contains a 10 mL oral syringe (with markings for each 0.5 mL) and a press-in bottle adapter.

1. Open the bottle and at first use, insert the press-in bottle adapter. The adapter remains in the bottle.
2. Insert the syringe into the adapter, invert the bottle and draw out the required dose.
3. Return bottle to upright position and remove the filled syringe.
4. Empty the syringe into the patient's mouth.
5. Replace the cap on the bottle and rinse the syringe.

If you forget to use MELATONIN-LINK

MELATONIN-LINK should be used regularly at the same time each day. If you forget to take a dose, it could be taken before going to sleep that night, but after this time, no other dose should be taken before the next evening. **Do not take a double dose to make up for the dose you missed.**

If you have trouble remembering to take MELATONIN-LINK, ask your pharmacist for some hints.

If you use too much MELATONIN-LINK

If you think that you have used too much MELATONIN-LINK, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia**), or
- phone the National Poisons Centre (**by calling 0800 POISON or 0800 764 766 in New Zealand**), or
- contact your doctor, 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-LINK?

Things you should do

Call your doctor straight away if you:

- Become pregnant while taking MELATONIN-LINK.

Remind any doctor, dentist or pharmacist you visit that you are using MELATONIN-LINK.

Things you should not do

- Do not give MELATONIN-LINK 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.

Driving or using machines

MELATONIN-LINK may cause drowsiness and may decrease alertness for several hours after intake. Therefore, this medicine should not be taken prior to driving or using machines.

MELATONIN-LINK makes you sleepy, and it could make you sleepy in the daytime as well.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Alcohol may cause drowsiness, so should not be taken together with MELATONIN-LINK.

Smoking

Tell your doctor if you smoke

Smoking may affect how well this medicine works.

Looking after your medicine

- Store below 25°C
- Store MELATONIN-LINK in original packaging to protect from light.

Follow the instructions on 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.

When to discard your medicine

Discard the oral solution 2 months after opening.

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
Body as a whole: • Generally feeling unwell • Feeling of weakness • Pain • Thirst • Fatigue • Changes in weight • Decreased appetite • Cough **Brain and nerves:** • Irritability • Nervousness • Abnormal dreams or nightmares • Anxiety • Difficultly sleeping • Sleepiness • Headache or migraine • Dizziness • Hyperactivity • Lethargy • Fainting • Disorientation • Confusion • Memory problems • Aggression • Depression • Restlessness • Tremor • Lightheadedness • Changes to libido (sex drive) • Pins and needles **Heart and vascular system:** • Bleeding or bruising more easily than normal • Hot flushes **Eyes, ears and mouth:** • Blurred vision or vision impairment • Watery eyes • Vertigo (spinning sensation) • Dry mouth • Excessive saliva productions • Bad breath **Gut and digestion:** • Nausea • Vomiting • Stomach pain • Diarrhoea • Constipation • Indigestion • Flatulence (wind) **Urinary:** • Wetting the bed • Excessing urination • Persistent urge to urinate • Pain and burning with urination **Muscles and bone:** • Muscle spasms • Muscle pain • Muscle weakness • Joint swelling and/or joint pain **Skin and nails:** • Dry skin • Rash • Itchy skin • Excessive sweating • Night sweats • Nail problems	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Immune system: • Allergic reaction such as shortness of breath, wheezing or difficulty breathing, swelling of the face lips, tongue or other parts of the body, hives, itching or skin rash **Infections:** • Frequent infections such as fever, chills, sore throat • Painful, blistering rash (shingles) **Heart and vascular system:** • Chest pain, or a feeling or tightness in the chest • Fast or irregular heartbeat	**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.**
Side effects affecting different parts of the body: • Persistent gut pain, nausea or vomiting (more than 1 week) • Blood in your stool or urine • Vomit containing what looks like coffee-grounds. • Persistent painful erection • Mouth ulcers, swelling of the tongue, swelling of the mouth • Seizure • Visual disturbances • Suicide attempt or ideation • Milky discharge from nipple	**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.**

Your doctor can only detect some side effects with a medical test. Attend any medical appointments needed to monitor these side effects.

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 (in Australia) or https://pophealth.my.site.com/carmreportnz/s/ (in New Zealand). 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 only available with a doctor's prescription.

What MELATONIN-LINK contains

Active ingredient (main ingredient)	Melatonin
Other ingredients (inactive ingredients) **Other ingredients (inactive ingredients**	Capsules: • Microcrystalline cellulose • Povidone • Maltodextrin • Magnesium stearate • Purified water • Titanium dioxide • Indigo carmine (FD&C Blue No. 2) (2 mg and 5 mg only) • Gelatin Oral Solution • Propylene glycol • Sorbitol • Sucralose • Strawberry flavour • Hydrochloric acid • Purified water
Potential allergens	Capsules: • Gelatin – may contain residual sulfites. Oral Solution • Sucralose • Sorbitol – 200mg/mL. Products containing sorbitol may have a laxative effects or cause diarrhoea.

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

What MELATONIN-LINK looks like

Capsules

2 mg: Opaque hard gelatin capsules with a white body and light blue cap. (AUST R 388301).

3 mg: Opaque hard gelatin capsules with a white body and white cap. (AUST R 388302).

5 mg: Opaque hard gelatin capsules with a light blue body and light blue cap. (AUST R 388303)

Oral Solution

A clear, colourless to yellowish solution with a strawberry scent. (AUST R 388304)

Who distributes MELATONIN-LINK

Sponsor

In Australia:
Link Medical Products Pty Ltd
5 Apollo Street
Warriewood NSW 2102
Australia

Ph: 1800 181 060
linkhealthcare.com.au

In New Zealand:
Link Pharmaceuticals Ltd
Suite 38, Level 8
139 Quay Street
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