VOQUILY® JET LAG RELIEF

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 VOQUILY JET LAG RELIEF?

VOQUILY JET LAG RELIEF contains the active ingredient melatonin. Each capsule contains 2 mg of melatonin.

VOQUILY JET LAG RELIEF is used for the short-term treatment of jet lag in adults 18 years of age and over.

For more information, see Section 1. Why am I using VOQUILY JET LAG RELIEF? in the full CMI.

2. What should I know before I use VOQUILY JET LAG RELIEF?

Do not use if you have ever had an allergic reaction to VOQUILY JET LAG RELIEF 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 VOQUILY JET LAG RELIEF? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VOQUILY JET LAG RELIEF 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 VOQUILY JET LAG RELIEF?

- The standard starting dose is 1 capsule once daily, before bed or preferred sleep time.
- VOQUILY JET LAG RELIEF should be taken on an empty stomach.

More instructions can be found in Section 4. How do I use VOQUILY JET LAG RELIEF? in the full CMI.

5. What should I know while using VOQUILY JET LAG RELIEF?

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

For more information, see Section 5. What should I know while using VOQUILY JET LAG RELIEF? 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.

VOQUILY® JET LAG RELIEF

Active ingredient: *melatonin*
Strength and dose form: 2 mg oral capsules

Consumer Medicine Information (CMI)

This leaflet provides important information about using VOQUILY JET LAG RELIEF. **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 VOQUILY JET LAG RELIEF.**

Where to find information in this leaflet:

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

1. Why am I using VOQUILY JET LAG RELIEF?

VOQUILY JET LAG RELIEF contains the active ingredient melatonin.

Each capsule contains 2 mg of melatonin.

Melatonin is a naturally occurring hormone produced in the body. It is one of the main hormones that helps you to sleep.

VOQUILY JET LAG RELIEF is used for the short-term treatment of jet lag in adults 18 years and older.

2. What should I know before I use VOQUILY JET LAG RELIEF?

Warnings

Do not use VOQUILY JET LAG RELIEF 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 or pharmacist 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 or pharmacist if you are pregnant or intend to become pregnant.

Melatonin is not recommended if you 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 or pharmacist **if you are breastfeeding or intend to breastfeed.**

Melatonin is not recommended if you 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 VOQUILY JET LAG RELIEF 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 VOQUILY JET LAG RELIEF.

4. How do I use VOQUILY JET LAG RELIEF?

How much to take

- The standard starting dose is 1 capsule once daily.

When to take VOQUILY JET LAG RELIEF

- Take the required dose at the preferred local sleep time of your travel destination.
- Taking it prior to departure may cause unwanted drowsiness and may be no more effective.
- Only use VOQUILY JET LAG RELIEF for a short period of time (no more than 5 days in a row).
- Avoid taking VOQUILY JET LAG RELIEF before 8 pm or after 4 am. This may make the medicine less effective.

How to take the VOQUILY JET LAG RELIEF capsules

VOQUILY JET LAG RELIEF capsules should be taken on an empty stomach, at least 1 hour after a meal. The capsules should be swallowed whole with a glass of water or juice.

If you forget to take VOQUILY JET LAG RELIEF

VOQUILY JET LAG RELIEF 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 VOQUILY JET LAG RELIEF, ask your pharmacist for some hints.

If you take too much VOQUILY JET LAG RELIEF

If you think that you have used too much VOQUILY JET LAG RELIEF, 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 VOQUILY JET LAG RELIEF?

Things you should do

Call your doctor straight away if you:

- Become pregnant while taking VOQUILY JET LAG RELIEF.

Remind any doctor, dentist or pharmacist you visit that you are using VOQUILY JET LAG RELIEF.

Things you should not do

- Do not give VOQUILY JET LAG RELIEF 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

VOQUILY JET LAG RELIEF 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.
VOQUILY JET LAG RELIEF 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 VOQUILY JET LAG RELIEF.

Smoking

Tell your doctor if you smoke.

Smoking may affect how well this medicine works.

Looking after your medicine

- Store below 25°C
- Store VOQUILY JET LAG RELIEF in original packaging to protect from light.

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.

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	**Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.**
Skin and nails: • Dry skin • Rash • Itchy skin • Excessive sweating • Night sweats • Nail problems	

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 **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.**

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.

7. Product details

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

What VOQUILY JET LAG RELIEF contains

Active ingredient (main ingredient)	Melatonin
Other ingredients (inactive ingredients)	**Capsules:** • Microcrystalline cellulose • Povidone • Maltodextrin • Magnesium stearate • Purified water • Titanium dioxide • Indigo carmine (FD&C Blue No. 2) (2 mg) • Gelatin
Potential allergens	Gelatin – may contain residual sulfites

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

What VOQUILY JET LAG RELIEF looks like

2 mg: Opaque hard gelatin capsules with a white body and light blue cap. (AUST R 485766).

Who distributes VOQUILY JET LAG RELIEF

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
Auckland 1010
New Zealand
Ph: +64 (9) 358 7146

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