

Package leaflet: information for the user

Davitamon Melatonin 1 mg  
Davitamon Melatonin 3 mg  
Davitamon Melatonin 5 mg

melatonin 1 mg/tablet  
melatonin 3 mg/tablet  
melatonin 5 mg/tablet

Read carefully the entire leaflet before you use this medicine because there is important information in for you. Use this medicine medication always exactly as described in this leaflet or as your doctor, or pharmacist you has told you.

- Keep this leaflet. Maybe has you need it later again needed.
- Do you still questions? Then contact your pharmacist.
- Do you experience one of the side effects that are in section 4 listed? Or do you get a side effect that is not in this leaflet listed ? Then contact your doctor or pharmacist pharmacist.
- Does your complaint after 6 days not lessen, or does it even worsen? Then contact your doctor.

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1. What is Davitamon Melatonin and what for is this medicine used?

The active ingredient in Davitamon Melatonin is melatonin. Melatonin is a hormone that naturally also by the body itself is produced.

Melatonin is used for the short-term treatment of jet lag in adults. Jet lag is a disorder of the sleep-wake rhythm, which can occur after crossing multiple time zones by air travel . one flight.

2. When may you this medicine not use or must you be extra careful with it?

When may you this medicine not use?

- You are allergic to one of the substances in this medicine. These substances can you find in section 6.

When must you take extra care be with this medicine?

Contact in the following cases your doctor, pharmacist or nurse before you use this medicine:

- If you are so drowsy that your safety is at risk can be ..
- a one liver disorder has. There are no data available on the effect of Davitamon Melatonin on individuals with a liver disease and therefore is in those cases use of this medication not recommended.
- If you epilepsy have. Due to use of melatonin can the number epileptic seizures increase.
- If you have an autoimmune disease. In patients with an autoimmune disease there are cases known of a worsening of the symptoms after taking melatonin. Discuss therefore with your doctor when you want to use this medication. Use of this medicine by people with an auto-immune disease is not recommended.
- If you have a high sugar level in the blood has or if you suffer from diabetes. If you melatonin take during a carbohydrate-rich meal (for example bread, potatoes, pasta, sugar) can the blood sugar level be disrupted. Do not use the product therefore not during the period of 2 hours before to 3 hours after the meal. Do you have severe impaired glucose intolerance or diabetes, then take the medication at least 3 hours after the meal.
- If you smoke. Because components of tobacco smoke the breakdown of melatonin by the liver can accelerate, may in individuals who smoke the effect of Davitamon Melatonin less strong be.

Children and adolescents up to 18 years

Do not give this medicine to children use of it in children is not studied and therefore the safety and efficacy of it not known.

Do you still other medicines?

Do you besides Davitamon Melatonin any other medicines, have you that recently done or is there the possibility that you in the near future other medications will use? Inform that then your doctor or pharmacist.

This is especially of importance when using use of sleeping aids, sedatives, medications against depression ( e.g.. fluvoxamine, desipramine, oxaprotiline ), estrogens (contraception or hormone therapy), blood thinners, medications to prevent epileptic seizures ( e.g.. carbamazepine), chlorpromazine medication against nausea ( e.g.. metoclopramide), cimetidine (drug against stomach acid), quinolone antibiotics and rifampicin, antihypertensive drugs (e.g.. nifedipine), drugs that contain caffeine and agents against skin problems (e.g.. 5- or 8-methoxypsoralen).

What should you pay attention to with food and drink?

Do not drink alcohol before, during or after the intake of melatonin.

Food can the level of melatonin in the blood increase. The use of melatonin together with the consumption of carbohydrate-rich meals (for example bread, potatoes, pasta, sugar) can the regulation of your blood sugar levels during several hours affect. Do not eat not in the period of 2 hours before to 2 hours after the taking of melatonin. For individuals with a too high sugar level in the blood or persons who suffer from diabetes, it applies that they may not eat in the may eating in the period of 2 hours before to 3 hours after the taking of melatonin.

### Pregnancy and breastfeeding

When you are pregnant , pregnant thinks to be, pregnant wants to become or breastfeeding , it is better not this medicine to use ..

### and and the use of machines

Davitamon Melatonin can drowsiness cause. If you are drowsy , you must not operate a vehicle drive or operate machines .If you are persistently drowsy , consult then your doctor.

### Davitamon Melatonin contains lactose

A Davitamon Melatonin 1 mg tablet contains 67.3 mg lactose monohydrate. A Davitamon Melatonin 3 mg tablet contains 65.3 mg lactose monohydrate. A Davitamon Melatonin 5 mg tablet contains 63.3 mg lactose monohydrate.

If you know that you certain sugars do not tolerate, please contact your doctor before you take this medicine ..

medicine contains less than 1 mmol sodium (23 mg) per 1 mg/3 mg/5 mg tablet, less than 1 mmol sodium (23 mg) per 1 mg/3 mg/5 mg tablet, means that it is in essence ' sodium-free ' is.sodium-free' is.

### 3. How to use you this medicine?

Use this medication always exactly as your doctor or pharmacist you that has told. Doubt you about the correct use? Then contact your doctor or pharmacist.

The recommended dosage is 1 to 5 mg per day, for 3 to 6 days.

The tablets can best be swallowed whole with some water to be swallowed. The score line is intended to break the tablet to be able to break if you have difficulty swallowing the whole tablet to swallow.

Take the tablets just before you want to sleep in, to start on the first day that the sleep rhythm is disturbed. Take the tablets not at the place of destination before 20.00 hours or after 04.00 hours. See also under 'What should you pay attention with food and drink?'

Take this medicine as short as possible in the dosage that the best relief provides of the symptoms.

### Use in children and adolescents under 18 years

Do not give this medicine not to children. The use of it in children is not studied and therefore the safety and efficacy of it not known.

### Have you taken too much of this medicine ingested?

After ingestion of more than the recommended daily dose you may feel extra sleepy feel and trouble experience from dizziness, headache and nausea. After intake of an overdose is no special treatment necessary.

Are you forgotten this medicine in to take?

If you have forgotten to a tablet in to take and you are therefore still awake, take this then anyway in. Take no double dose to make up a missed dose in to catch up.

If you stops with the taking of this medicine

You can always stop using this medicine . There areno adverse effects adverse effects known as the treatment is interrupted or prematurely is terminated. Regarding the use of melatonin there so far no cases of withdrawal symptoms known that are caused by the discontinuation of the treatment.

Do you have any questions about the use of this medicine? Then contact your doctor or pharmacist.

#### 4. Possible side effects

Like any medication can also this medication have side effects, although not everyone experiences them with make.

During the use of melatonin are the following side effects reported:

- Abnormal dreams
- Abnormal behavior
- Abnormal feeling
- Abnormal stool
- Asthma
- Bedwetting
- Pallor
- Nosebleed
- Vomiting
- Abdominal pain
- Constipation
- Depression
- Depressive (melancholic) mood
- Disorientation
- Diarrhea
- Dizziness
- Pressure behavior
- Dizziness
- Dizziness postural
- Epilepsy
- Yawning
- Lack of emotion
- Irritability (irritability)
- Weight loss
- Weight gain
- Hallucinations
- Palpitations
- Coughing
- Headache

- Skin irritation
- Skin rash
- Crying
- Hyperactivity
- Itching
- Shortness of breath
- Cold feeling
- Low blood pressure
- Lethargy
- Migraine
- Nausea
- Difficulty with swallowing
- Nightmares
- Discomfort in the abdomen
- Eye disorder
- Ear-/nose-/throat problems
- Regurgitation
- Hypersensitivity
- Excessive sweating
- Excessive drowsiness
- Pain on the chest
- Restlessness
- Sharp defined round reddish-brown spots on the skin
- Sleepwalking
- Insomnia
- Poor sleep quality
- Rapid heart rate
- Mood changes
- Severely itchy spots or bumps (prurigo)
- Increase in seizures Tremor
- Altered
- liver function values in the blood blood
- Lowered body temperature
- Decreased appetite
- Reduced visual acuity
- Fatigue
- Confusion
- Blotchy skin
- Heavy feeling in the head

Reporting of side effects Do you experience

any side effects from side effects, please contact your doctor or pharmacist. This applies also to possible side effects that are not in this leaflet . You can report side effects also directly report via the Dutch Side Effects Center Lareb. Website: [www.lareb.nl](http://www.lareb.nl).

By reporting side effects ,you can help us gain more information to obtain about the safety of this medication.

5. How do you store this medicine ? Out of the

sight and reach of children keep ..

Store below 25°C. Store in the original packaging to protect from light.

Expiry date

Do not use this medicine after the expiry the expiry date. It is to find on the plastic tablet container, the box and the blister packs after 'EXP'. There is a month and a year. The last day of that month is the expiry date.

The shelf life after opening of the tablet container is 1 month.

Take this medicine not in if you see that the tablets discolored or damaged are.

Do not flush medicines not down the sink or the toilet and throw them not in the trash can. Ask your pharmacist what to do with medicines you should do that you no longer use. They become then on a responsible manner destroyed and do not into the environment end up.

6. Contents of the packaging and other information

Which substances are in this medicine?

The active ingredient in this medicine is melatonin.

The other ingredients (excipients) in this substance are: silicified microcrystalline cellulose, lactose monohydrate, sodium starch glycolate type A, talc and magnesium stearate.

What does Davitamon Melatonin look like in how much is in a package?

Davitamon Melatonin 1 mg, tablets are white to off-white white hexagonal tablets, with a score line on one side and an inscription "MELA 1" on the other side.

Davitamon Melatonin 3 mg, tablets are white to broken white oblong tablets, with a score line on one side and an inscription "MELA 3" on the other side.

Davitamon Melatonin 5 mg, tablets are white to off-white white round tablets, with a score line on one side and an inscription "MELA 5" on the other side.

The tablets are delivered:

- in a cardboard box with 10, 15, 20 or 30 tablets in blister packs
- or in a plastic tablet container with 30 tablets.

Registered under under

Davitamon Melatonin 1 mg RVG 124675

Davitamon Melatonin 3 mg RVG 124676

Davitamon Melatonin 5 mg RVG 124677

Holder of the license for the in the market introduction and manufacturer Holder of the license for the in the market introduction

Omega Pharma Nederland B.V.

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3062 CE Rotterdam

Manufacturer  
Omega Pharma Manufacturing GmbH & Co. KG Benzstraße 25  
71083 Herrenberg, Germany

For all information regarding this medication contact the local representative of the local representative of the holder of the authorization for placing on the market ..

leaflet is for the last approved in April 2025. Other

sources of information information sources

More information about this medicine is available on the website of the Medicines Evaluation Board for Evaluation of Medicines: [www.cbg-meb.nl](http://www.cbg-meb.nl).