

Package leaflet: Information for the user

Melatonine Orifarm 2 mg, filmomhulde tabletten

melatonin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Only relevant for OTC:

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

What is in this leaflet

1. What Melatonine Orifarm is and what it is used for
2. What you need to know before you take Melatonine Orifarm
3. How to take Melatonine Orifarm
4. Possible side effects
5. How to store Melatonine Orifarm
6. Contents of the pack and other information

1. What Melatonine Orifarm is and what it is used for

Melatonine Orifarm contains the active substance melatonin. Melatonine Orifarm can be used for treatment of jet-lag in adults. Jet-lag can be recognized by sleep disturbances, daytime tiredness, fatigue, mild mental impairment, irritability and digestive system disturbances experienced after flying.

How Melatonine Orifarm works

Melatonin is a hormone produced by the body that synchronises the body's biological day-and-night rhythm. The biological rhythm can be disturbed by travelling across time zones. This is known as jet-lag. The symptoms and their severity vary between individuals, but are generally worse and last longer the more time zones are crossed. Melatonine Orifarm can help restore the normal day-and-night rhythm and reduce the symptoms.

Only relevant for OTC:

You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

2. What you need to know before you take Melatonine Orifarm

Do not take Melatonine Orifarm:

- if you are allergic to melatonin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Melatonine Orifarm.

- if you have epilepsy. Melatonin may increase the seizure frequency in patients with epilepsy
- if you have an autoimmune disease (where the body is 'attacked' by its own immune system)
- if you have diabetes or impaired glucose tolerance, as this medicine may increase the level of glucose in your blood
- if you suffer from impaired liver- or kidney function
- if you smoke. Smoking may reduce the effect of Melatonine Orifarm as components of tobacco smoke can increase the breakdown of melatonin by the liver.

Children and adolescents

Do not give this medicine to children and adolescents between 0 and 18 years as its safety and efficacy are unknown.

Other medicines and Melatonine Orifarm

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- fluvoxamine (used for the treatment of depression and obsessive-compulsive disorder)
- psoralens (used for the treatment of skin disorders e.g. psoriasis)
- cimetidine (used for the treatment of stomach problems such as ulcers)
- estrogens (used in contraceptives or hormone replacement preparations)
- quinolones (used in the treatment of bacterial infections)
- rifampicin (used in the treatment of bacterial infections)
- carbamazepine (used in the treatment of epilepsy)
- benzodiazepines and non-benzodiazepine hypnotics (medicines used to induce sleep, e.g. midazolam, temazepam, and zaleplon, zolpidem, zopiclone), as melatonin may enhance the sedative effect of such medicines, and may enhance certain side effects of zolpidem (morning sleepiness, nausea, confusion)
- warfarin (anticoagulant), as melatonin may influence the effect of the anticoagulant warfarin.

Melatonine Orifarm with food, drink and alcohol

Melatonine Orifarm should not be taken with food.

As alcohol can impair sleep and potentially worsen certain symptoms of jet-lag (e.g. headache, morning fatigue, concentration) it is recommended that alcohol is not consumed while taking this medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Melatonine Orifarm 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.

Breast-feeding

Melatonine Orifarm is not recommended if you are breast-feeding. Melatonin is excreted in human milk, and a risk to the breast-fed infant or child cannot be excluded.

Fertility

Melatonine Orifarm is not recommended in women and men planning to have a baby as there is insufficient information on the effects of melatonin on female and male fertility.

Driving and using machines

Melatonine Orifarm 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.

3. How to take Melatonine Orifarm

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Only relevant for OTC:

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults and elderly is 1 tablet, daily for maximum 5 days. When the effect of Melatonine Orifarm is inadequate, 2 tablets can be taken simultaneously.

The first dose should be taken on arrival at destination at your usual bed-time. Intake on the following days should also be at your usual bed-time. The tablet(s) should not be taken before 20:00 hr or after 04:00 hr.

The tablets should be swallowed whole with water. Food should not be consumed 2 hours before or 2 hours after intake of Melatonine Orifarm.

Melatonine Orifarm may be taken for a maximum of 16 treatment periods per year.

The tablet can be divided into equal doses.

If you take more Melatonine Orifarm than you should

If you have taken more Melatonine Orifarm than recommended and you do not feel well, please contact your doctor, hospital or pharmacy.

The most common symptoms of overdose are drowsiness, headache, dizziness and nausea.

If you forget to take Melatonine Orifarm

If you forget to take a dose at bedtime and wake during the night you may take the forgotten dose but at no later than 04:00 hr.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Melatonine Orifarm

If you stop taking Melatonine Orifarm, it will not have any harmful effects or withdrawal symptoms.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following serious side effects stop taking this medicine and contact your doctor immediately:

Rare side effects (may affect up to 1 in 1,000 people):

- General malaise, prone to inflammation (infections), especially sore throat and fever due to changes in the blood (low levels of white blood cells).
- Bleeding from the skin and mucous membranes and bruising due to changes in the blood (low platelet count).
- Fainting.

Other possible side effects:

Common side effects (may affect up to 1 in 10 people):

- Headache, drowsiness.

Uncommon side effects (may affect up to 1 in 100 people):

- Irritability, nervousness, restlessness, abnormal dreams, anxiety.
- Dizziness.
- High blood pressure.
- Abdominal pain, indigestion, mouth ulceration, dry mouth, nausea.
- Itching, rash, dry skin.
- Excretion of glucose in the urine, excess protein in the urine.
- Chest pain, feeling unwell.
- Weight increase.

Rare side effects (may affect up to 1 in 1,000 people):

- Increased risk of atherosclerosis due to increased fat (triglycerides) in the blood.
- Altered mood, aggression, disorientation, increased sex drive.
- Memory impairment, restless leg syndrome, 'pins and needles' sensation.
- Visual impairment including blurred vision.
- Watery eyes.
- Feeling your heartbeat.
- Hot flushes.
- Vomiting, wind, excess saliva, bad breath, inflammation of the stomach lining.
- Nail disorder.
- Pain in the joints, muscle spasms.
- Increased urine volume, blood in the urine.
- Prolonged, painful erection, inflammation of the prostate gland.
- Thirst.
- Abnormal levels of electrolytes in the blood.

Not known (frequency cannot be estimated from the available data):

- Hypersensitivity reaction.
- Frequent urination, thirst, fatigue due to high blood glucose levels.
- Swelling of the lining of the mouth or tongue.
- Secretion of milk from the breasts.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Melatonine Orifarm

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the container after EXP. The expiry date refers to the last day of that month.

Store in the original container in order to protect from light and moisture.
This medicine does not require any special temperature storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Melatonine Orifarm contains

- The active substance is melatonin 2 mg.
- The other ingredients are cellulose, microcrystalline (E460); maltodextrin; silica, colloidal anhydrous (E551); magnesium stearate (E470b); croscarmellose sodium (E468); hypromellose (E464).

What Melatonine Orifarm looks like and contents of the pack

Appearance

Melatonine Orifarm are white/off-white to beige, biconvex, circular shaped film-coated tablets with a score line and “2” on one side. Diameter: 8 mm.

Content of the pack

Tablet container with desiccant closure.

Pack size: 30 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Orifarm Generics A/S

Energivej 15

5260 Odense S

Denmark

Manufacturer

Orifarm Generics A/S

Energivej 15

5260 Odense S

Denmark

or

Viminco A/S

Lodshusvej 11

4230 Skælskør

Denmark

In het register ingeschreven onder:

RVG 125769

This medicinal product is authorised in the Member States of the EEA under the following names:

Netherlands Melatonine Orifarm

Denmark Melatonin Alternova

Sweden Melatonin Orifarm

Norway Melatonin Orifarm

Deze bijsluiter is voor het laatst goedgekeurd in april 2021