

Package leaflet: Information for the user

Melatonin Pharma Nord 3 mg, film-coated tablets melatonin

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 have 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 or pharmacist. 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.

What is in this leaflet

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

1. What Melatonin Pharma Nord is and what it is used for

Melatonin Pharma Nord contains the active substance melatonin. Melatonin is a hormone produced naturally in the body. This hormone helps regulate the body's day- and night rhythm.

Melatonin Pharma Nord can be used for:

- Short-term treatment of jet-lag, in adults only. Jet-lag refers to the symptoms caused by the time difference when travelling across several time zones.

How Melatonin Pharma Nord works

Melatonin is a hormone produced by the body that synchronizes the body's biological day-and-night rhythm. The biological rhythm can be disturbed by travelling across time zones. This is known as a jet-lag.

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

2. What you need to know before you take Melatonin Pharma Nord

Do not take Melatonin Pharma Nord

- 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 or pharmacist before taking Melatonin Pharma Nord

- if you suffer from seizures. Melatonin may increase seizure frequency, for example 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. Please ensure that you do not take this medicine 2 hours before a meal and wait at least 3 hours after a meal if you suffer from diabetes.

- if you suffer from moderately to significantly impaired liver function or significantly impaired kidney function.
- if you smoke. Smoking may reduce the effect of Melatonin Pharma Nord as components of tobacco smoke can increase the breakdown of melatonin by the liver.
- if you suffer from hypertension and are being treated for this. Melatonin may reverse the beneficial effects of blood pressure-lowering medicines.
- This medicine can make you feel drowsy, you should be careful if the drowsiness affects you as it may impair your ability on tasks such as driving.

Children and adolescents

Do not give this medicine to children and adolescents between 0 and 18 years as its safety and effectiveness in the short-term treatment of jet-lag are unknown.

Other medicines and Melatonin Pharma Nord

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), as fluvoxamine may increase the effect of melatonin
- Imipramine (used in the treatment of depression), as both medicines taken together enhance feelings of drowsiness and can cause difficulty in performing tasks.
- Thioridazine (used in the treatment of mental/mood disorders), as both medicines taken together enhance feelings of drowsiness and difficulty in performing tasks.
- Psoralens (used for the treatment of skin disorders e.g. psoriasis), as psoralens may increase the effect of melatonin
- Cimetidine (used for the treatment of stomach problems such as ulcers), as cimetidine may increase the effect of melatonin
- Oestrogens (used in contraceptives or hormone replacement therapy), as oestrogens may increase the effect of melatonin
- Quinolones (used in the treatment of bacterial infections), as quinolones may increase the effect of melatonin
- Rifampicin (used in the treatment of bacterial infections), as rifampicin may decrease the effect of melatonin
- Carbamazepine (used in the treatment of epilepsy), as carbamazepine may decrease the effect of melatonin
- Warfarin and other blood-thinning medicines e.g. dabigatran, rivaroxaban, apixaban, edoxaban, as melatonin may interfere with the effect of these medicines. It may be necessary to measure the time for the blood to clot, also known as INR-test.
- 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)
- Nifedipine and other calcium channel blocker medicines (used in the treatment of high blood pressure), as both medicines taken together may increase blood pressure.
- Caffeine (stimulant), as melatonin interacts with caffeine.

Melatonin Pharma Nord with food and alcohol

- This medicine should not be taken with food (see section 3).
- As alcohol can impair sleep and potentially worsen certain symptoms of jet-lag (e.g. headache, morning fatigue, impaired concentration) it is recommended that alcohol is not consumed while taking this medicine.
- Consuming alcohol while taking this medicine may lead to increased drowsiness.

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

Melatonin Pharma Nord 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. If you are a woman of childbearing potential you have to use contraception.

Breast-feeding

Melatonin Pharma Nord is not recommended if you are breast-feeding. Melatonin passes into human milk, and a risk to the breast-fed infant or child cannot be excluded.

Fertility

Melatonin Pharma Nord 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

Melatonin Pharma Nord 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 Pharma Nord contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Melatonin Pharma Nord

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 a maximum of 5 days. When the effect of Melatonin Pharma Nord is inadequate, 2 tablets can be taken simultaneously the following evening. The dose that reduces symptoms sufficiently should be taken for the shortest period necessary.

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. Tablet(s) should not be taken before 20:00 h or after 04:00 h.

Tablets should be swallowed whole with water or other liquid (e.g. milk, fruit juice). Food should not be consumed at least 2 hours before or at least 2 hours after intake of Melatonin Pharma Nord. If you have impaired glucose tolerance or diabetes Melatonin Pharma Nord should ideally not be taken at least 3 hours after a meal.

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

If you take more Melatonin Pharma Nord than you should

If you have taken more Melatonin Pharma Nord 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 Melatonin Pharma Nord

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

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

If you stop taking Melatonin Pharma Nord

If you stop taking this medicine, 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 or pharmacist.

4. Possible side effects

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

Serious side effects

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

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

- Chest pain

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

- Reduced number of white blood cells in the blood
- Reduced number of blood platelets, which increases the risk of bleeding or bruising
- Disorientation
- Fainting
- Visual impairment, including blurred vision
- Chest pain due to angina pectoris
- Feeling your heartbeat ('pounding chest')
- Blood (red blood cells) in the urine

Not known (frequency cannot be estimated from available data)

- Severe allergic reaction resulting in swelling of the tongue or lining of the mouth

Other side effects

If you experience any of the following other side effects contact your doctor or pharmacist:

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

- Irritability, nervousness, restlessness, sleeplessness, abnormal dreams, nightmares, anxiety
- Migraine, lethargy
- Restlessness associated with increased activity
- Dizziness
- High blood pressure
- Abdominal pain, upper abdominal pain, indigestion, mouth ulceration, dry mouth, nausea
- Changes in the composition of your blood that can cause yellowing of the skin and eyes
- Inflammation of the skin, night sweats, itching, rash, dry skin
- Pain in the extremities
- Excretion of glucose in the urine, excess protein in the urine
- Menopausal symptoms in women
- Feeling unwell
- Abnormal results in liver function tests

- Weight increase

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

- Herpes zoster
- High levels of certain fat molecules (triglycerides) in the blood
- Low calcium or sodium levels in the blood
- Altered mood, aggression, crying, stress symptoms, early morning awakening, increased sex drive
- Depression
- Memory impairment, disturbance in attention, dreaming state, restless legs syndrome, poor quality sleep, 'pins and needles' sensation
- Watery eyes
- Vertigo (a feeling of dizziness or “spinning”), dizziness when standing or sitting, vertigo positional
- Hot flushes
- Acid reflux, gastrointestinal disorder, blistering in the mouth, tongue ulceration, stomach upset
- Vomiting, abnormal bowel sounds, wind, excess saliva, bad breath, abdominal discomfort, gastric disorder, inflammation of the stomach lining
- Eczema, erythema, dermatitis of the hands, psoriasis, rash generalised, rash pruritic, nail disorder
- Arthritis, muscle spasms, neck pain, night cramps
- Passing large volumes of urine, need to urinate at night
- Prolonged erection that might be painful, inflammation of the prostate gland
- Tiredness, pain, thirst
- Increased liver enzymes, abnormal levels of electrolytes in the blood, laboratory test abnormal

Not known (frequency cannot be estimated from available data)

- Hypersensitivity reactions
- High blood glucose level
- Flow of milk from the breasts (also in men)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You or your relatives can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Melatonin Pharma Nord

- 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 outer carton and blister after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special temperature storage conditions.
- This medicine should be stored in the original packaging in order to protect from light.

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

6. Contents of the pack and other information

What Melatonin Pharma Nord contains

- The active substance is melatonin. Each tablet contains 3 mg melatonin.
- The other ingredients are: *Tablet core*: magnesium stearate, colloid silica anhydrous, maltodextrin, microcrystalline cellulose, croscarmellose sodium. *Film-coating*: hypromellose.

What Melatonin Pharma Nord looks like and contents of the pack

Round, biconvex, clear-coated, white to off-white tablet. Size 7.5 mm.

Blister pack containing 10, 20 or 30 film-coated tablets, in carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Pharma Nord ApS
Tinglykke 4-6
6500 Vojens
Denmark

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium	Melatonine Pharma Nord 3 mg comprimés pelliculés / filmomhulde tabletten / Filmtabletten
Denmark	Melatonin Pharma Nord
Estonia	Melatonin Pharma Nord 3 mg õhukese polümeerikattega tabletid
Finland	Melatonin Pharma Nord 3 mg, kalvopäällysteinen tabletti / filmdragerade tablett
Germany	Melatonin Pharma Nord 3 mg Filmtabletten
Hungary	Melatonin Pharma Nord 3 mg filmtabletta
Ireland	Melatonin Pharma Nord 3 mg film-coated tablets
Latvia	Melatonin Pharma Nord 3 mg apvalkotās tabletes
Lithuania	Melatoninas Pharma Nord 3 mg plėvele dengtos tabletės
Luxembourg	Melatonine Pharma Nord 3 mg comprimés pelliculés / filmomhulde tabletten / Filmtabletten
Netherlands	Melatonine Pharma Nord 3 mg filmomhulde tablet
Norway	Melatonin Pharma Nord
Poland	Melatonina Pharma Nord 3 mg tabletki powlekane
Portugal	Melatonina Pharma Nord 3 mg, comprimidos revestidos por película
Slovenia	Melatonin Pharma Nord 3 mg filmsko obložene tablete
Spain	Melatonite 3 mg comprimidos recubiertos con película
Sweden	Melatonin Pharma Nord 3 mg filmdragerade tabletter
United Kingdom (NI)	Melatonin 3 mg, film-coated tablets

Formatted: Portuguese (Portugal)

This leaflet was last revised in 04/2026.