

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 after 5 days.

What is in this leaflet

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

Melatonin Pharma Nord contains the active substance melatonin. Melatonin Pharma Nord can be used for treatment of short-term 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 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. The symptoms and their severity vary between individuals, but are generally worse and last longer the more time zones are crossed. Melatonin Pharma Nord can help restore the normal day-and-night rhythm and reduce the symptoms.

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 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
- 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 (used as a blood thinner), as melatonin may interfere with the effect of warfarin
- 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)

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 hr or after 04:00 hr.

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.

Melatonin Pharma Nord 3 mg may be taken for a maximum of 16 treatment periods per year.

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 hr.

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
- 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:

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, upper abdominal pain, indigestion, mouth ulceration, dry mouth, nausea
- Itching, rash, dry skin
- Excretion of glucose in the urine, excess protein in the urine
- Feeling unwell
- Weight increase

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

- High levels of certain fat molecules (triglycerides) in the blood
- Altered mood, aggression, increased sex drive
- Memory impairment, restless legs syndrome, 'pins and needles' sensation
- Watery eyes

- Hot flushes
- Vomiting, wind, excess saliva, bad breath, inflammation of the stomach lining
- Nail disorder
- Arthritis, muscle spasms
- Passing large volumes of urine
- Prolonged erection that might be painful, inflammation of the prostate gland
- Thirst
- Abnormal levels of electrolytes in the blood

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 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 péliculés / filmomhulde tabletten / Filmtabletten
Estonia	Melatoniin Pharma Nord 3 mg õhukese polümeerikattega tabletid
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
Netherlands	Melatonine Pharma Nord 3 mg filmomhulde tablet
Poland	Melatonina Pharma Nord 3 mg tabletki powlekane
Portugal	Melatonina Pharma Nord 3 mg, comprimidos revestidos por película
Spain	Melatonite 3 mg comprimidos recubiertos con película
United Kingdom (NI)	Syncrodin 3 mg, film-coated tablets