Package leaflet: Information for the patient

Melnite 2 mg prolonged-release tablets
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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Melnite is and what it is used for
The active substance of Melnite, melatonin, belongs to a natural group of hormones produced by the body.

Melnite is used on its own for the short-term treatment of primary insomnia (persistent difficulty in getting to sleep or staying asleep, or poor quality of sleep) in patients aged 55 years and older. 'Primary' means that the insomnia does not have any identified cause, including any medical, mental or environmental cause.

2. What you need to know before you take Melnite

Do not take Melnite
- 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 Melnite.

- If you suffer from liver or kidney problems. No studies on the use of Melnite in people with liver or kidney diseases have been performed, you should speak to your doctor before taking Melnite as its use is not recommended.
- If you have been told by your doctor that you have an intolerance to some sugars.
- If you have been told you suffer from an autoimmune disease (where the body is 'attacked' by its own immune system). No studies on the use of Melnite in people with auto-immune diseases have been performed; therefore, you should speak to your doctor before taking Melnite as its use is not recommended.
- Melnite 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.
- Smoking may make Melnite less effective, because the components of tobacco smoke can increase the breakdown of melatonin by the liver.

Children and adolescents
Do not give this medicine to children between the ages of 0 to 18 years as it has not been tested and its effects are unknown. Another medicine containing melatonin may be more appropriate for administration to children between the ages of 2 to 18 – please ask your doctor or pharmacist for advice.

Other medicines and Melnite
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. These medicines include:

- Fluvoxamine (used for the treatment of depression and obsessive compulsive disorder), psoralens (used in the treatment of skin disorders e.g. psoriasis), cimetidine (used in the treatment of stomach problems such as ulcers), quinolones and rifampicin (used in the treatment of bacterial infections), oestrogens (used in contraceptives or hormone replacement therapy) and carbamazepine (used in the treatment of epilepsy).
- Adrenergic agonists/antagonists (such as certain types of medicines used to control blood pressure by constricting blood vessels, nasal decongestants, blood pressure lowering medicines), opiate agonists/antagonists (such as medicinal products used in the treatment of drug addiction), prostaglandin inhibitors (such as nonsteroidal anti-inflammatory medicines), antidepressant medication, tryptophan and alcohol.
- Benzodiazepines and non-benzodiazepine hypnotics (medicines used to induce sleep such as zaleplon, zolpidem and zopiclone)
- Thioridazine (for the treatment of schizophrenia) and imipramine (for the treatment of depression).

Melnite with food, drink and alcohol
Take Melnite after you have eaten. Do not drink alcohol before, during or after taking Melnite, because it reduces the effectiveness of Melnite.

Pregnancy and breast-feeding
Do not take Melnite if you are pregnant, think you may be pregnant, trying to become pregnant or breast-feeding. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Melnite may cause drowsiness. If you are affected, you should not drive or operate machinery. If you suffer from continued drowsiness, then you should consult your doctor.

Melnite contains lactose monohydrate
Melnite contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Melnite

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

The recommended dose is one Melnite tablet (2 mg) taken daily by mouth, after food, 1-2 hours before bedtime. This dosage may be continued for up to thirteen weeks.

You should swallow the tablet whole. Melnite tablets should not be crushed or cut in half.

If you take more Melnite than you should
If you have accidentally taken too much of your medicine, contact your doctor or pharmacist as soon as possible.

Taking more than the recommended daily dose may make you feel drowsy.

If you forget to take Melnite
If you forget to take your tablet, take another as soon as you remember, before going to sleep, or wait until it is time to take your next dose, then go on as before.

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

If you stop taking Melnite
There are no known harmful effects if treatment is interrupted or ended early. The use of Melnite is not known to cause any withdrawal effects after treatment completion.

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.

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

Uncommon: (may affect up to 1 in 100 people)
- Chest pain

Rare: (may affect up to 1 in 1000 people)
- Loss of consciousness or fainting
- Severe chest pain due to angina
- Feeling your heartbeat
- Depression
- Visual impairment
- Blurred vision
- Disorientation
- Vertigo (a feeling of dizziness or "spinning")
- Presence of red blood cells in the urine
- Reduced number of white blood cells in the blood
- Reduced blood platelets, which increases risk of bleeding or bruising
- psoriasis

If you experience any of the following nonserious side effects contact your doctor and/or seek medical advice:

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

Irritability, nervousness, restlessness, insomnia, abnormal dreams, nightmares, anxiety, migraine, headache, lethargy (tiredness, lack of energy), restlessness associated with increased activity, dizziness, tiredness, high blood pressure, upper abdominal pain, indigestion, mouth ulceration, dry mouth, nausea, changes in the composition of your blood which could cause yellowing of the skin or eyes, inflammation of the skin, night sweats, itching, rash, dry skin, pain in extremities, menopausal symptoms, feeling of weakness, excretion of glucose in the urine, excess proteins in the urine, abnormal liver function and weight increase.

Rare: (may affect up to 1 in 1000 people)

Shingles, high level of fatty molecules in the blood, low serum calcium levels in the blood, low sodium levels in the blood, altered mood, aggression, agitation, crying, stress symptoms, early morning awakening, increased sex drive, depressed mood, memory impairment, disturbance in

attention, dreamy state, restless legs syndrome, poor quality sleep, 'pins and needles' feeling, watery eyes, dizziness when standing or sitting, hot flushes, acid reflux, stomach disorder, blistering in the mouth, tongue ulceration, stomach upset, vomiting, abnormal bowel sounds, wind, excess saliva production, bad breath, abdominal discomfort, gastric disorder, inflammation of the stomach lining, eczema, skin rash, hand dermatitis, itchy rash, nail disorder, arthritis, muscle spasms, neck pain, night cramps, prolonged erection that might be painful, inflammation of the prostate gland, tiredness, pain, thirst, passing large volumes of urine, urinating during the night, increased liver enzymes, abnormal blood electrolytes and abnormal laboratory tests.

Frequency not known: (cannot be established from the available data)

Hypersensitivity reaction, swelling of mouth or tongue, swelling of the skin and abnormal milk secretion.

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 can also report side effects directly via the national reporting system listed below:

Ireland:
HPRA Pharmacovigilance, Website: www.hpra.ie.

5. How to store Melnite

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 carton and blister after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C. Keep blisters in the outer carton, in order to protect from light.

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 to protect the environment.

6. Contents of the pack and other information

What Melnite contains
- The active substance is melatonin. Each prolonged-release tablet contains 2 mg melatonin.
- The other ingredients are ammonio methacrylate copolymer (Type B), calcium hydrogen phosphate dihydrate (E341), lactose monohydrate "(see section 2)", silica colloidal anhydrous (E551), talc (E553b), magnesium stearate.

What Melnite looks like and contents of the pack
Melnite 2 mg prolonged-release tablets are available as white to off-white, round (8.0 ± 0.3 mm diameter), bi-convex, tablets. The tablets are packed in white opaque, PVC/PVDC blister packs sealed with aluminium foil. The blisters are then packed in cardboard box. Each pack consists of two blister strips containing 15 tablets (30 tablets).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Pinewood Laboratories Ltd.,
Ballymacarbry,

Clonmel,
Co. Tipperary,
Ireland.

Manufacturer:

Przedsiębiorstwo Farmaceutyczne LEK-AM Sp. z o.o.,
14A Ostrzykowizna Street, 05-170 Zakroczym, POLAND.

This leaflet was last revised in September 2024.