

Package leaflet: Information for the user
Neomel 1mg/ml Oral Solution

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.

The name of your medicine is Neomel 1mg/ml Oral Solution, it will be referred to as Neomel Oral Solution for ease hereafter.

What is in this leaflet

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

1. What Neomel Oral Solution is and what it is used for

Neomel Oral Solution is a formulation which contains the active substance melatonin. Neomel Oral Solution can be used for treatment of jet-lag in adults only. Jet-lag can be recognised by sleep disturbances, daytime tiredness, fatigue, mild mental impairment, irritability and digestive system disturbances experienced after flying.

How Neomel Oral Solution 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 jet-lag. The symptoms and their severity vary between individuals, but are generally worse and last longer the more time zones are crossed. Neomel Oral Solution 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 use Neomel Oral Solution

Do not take Neomel Oral Solution

- 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 Neomel Oral Solution:

- If you have epilepsy. Melatonin may increase 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 significantly impaired liver function or kidney function
- If you smoke. Smoking may reduce the effect of Neomel Oral Solution as components of tobacco smoke can increase the breakdown of melatonin by the liver.

Care should be taken when changing between formulations/products as changing formulations may increase the risk of drowsiness.

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 Neomel Oral Solution

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 preparations), 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
- 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 drugs, and may enhance certain side effects of zolpidem (morning sleepiness, nausea, confusion)
- Warfarin (anticoagulants), as melatonin may influence the effect of the anticoagulant warfarin.

Neomel Oral Solution with food, drink 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, 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.

If you are a woman of childbearing potential taking this medicine you have to use contraception.

Pregnancy

Neomel Oral Solution 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

Neomel Oral Solution is not recommended if you are breast-feeding. Melatonin is excreted in human milk, and a risk to the suckling child cannot be excluded.

Fertility

Neomel Oral Solution 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

Neomel Oral Solution 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.

Neomel Oral Solution contains sorbitol and propylene glycol

This medicine contains 300 mg sorbitol and 150 mg propylene glycol in each ml.

Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine.

Neomel Oral Solution contains forms of benzoates

This medicine contains methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

Neomel Oral Solution contains tri-sodium citrate.

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

3. How to use Neomel Oral Solution

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 for adults and elderly is 3 mg (3 ml) daily for a maximum of 5 days.

When the effect of Neomel Oral Solution is inadequate, 6 mg (6 ml) can be taken.

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 oral solution should not be taken before 20:00 hr or after 04:00 hr.

Food should not be consumed 2 hours before or 2 hours after intake of Neomel Oral Solution.

Neomel Oral Solution may be taken for a maximum of 16 treatment periods per year.

Method of administration

Neomel Oral Solution is for oral use only.

A "Press-In" Bottle Adapter (PIBA) and a 5 ml graduated oral syringe with intermediate graduations of 0.5 ml is provided with the product.

1. Remove the child-resistant, tamper evident cap from the bottle by pushing it down and turning it anti-clockwise (**Figure 1**)
2. Push the PIBA into the neck of the product bottle (**Figure 2**)
3. With the plunger of the syringe pressed completely down, insert the syringe into the PIBA (**Figure 3**) and draw out the required volume from the inverted bottle (**Figure 4**)
4. Remove the filled syringe from the bottle in the upright position (**Figure 5**)
5. Discharge the syringe contents into the mouth (**Figure 6**)
6. Wash the syringe inside and out by rinsing in water and replace the cap on the bottle (**Figure 7**)



Figure 1

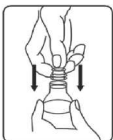


Figure 2

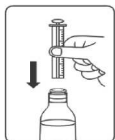


Figure 3

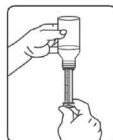


Figure 4



Figure 5



Figure 6

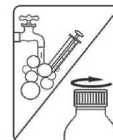


Figure 7

If you take more Neomel Oral Solution than you should

If you have taken more Neomel Oral Solution 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 Neomel Oral Solution

If you forget to take your 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 missed dose.

If you stop taking Neomel Oral Solution

If you stop taking Neomel Oral Solution, it will not have any harmful effects or withdrawal symptoms.

If you have any further questions on the use of this product, 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, tell your doctor immediately and stop taking the medicine.

Frequency not known:

- Hypersensitivity reaction, (allergy like reactions such as itching, difficulties to breathe).
- Swelling of deeper layers of skin (angioedema)
- Swelling in mouth and tongue (oedema)

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

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

- Headache
- Sleepiness

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

- Irritation, nervousness, restlessness,
- Sleeplessness (insomnia), abnormal dreams, nightmares, night sweats, anxiety, anxious restlessness, physical weakness, lack of energy and enthusiasm,
- Migraine
- Dizziness
- High blood pressure
- Mouth ulceration
- Dry mouth
- Nausea, abdominal pain
- Skin disorders (dermatitis, pruritus, rash, dry skin)
- Pain in arms and legs
- Menopausal symptoms
- Chest pain
- Excretion of glucose in the urine, excess proteins in the urine
- Changes in the composition of your blood which can cause yellowing of the skin and eyes
- Abnormal liver function tests
- Increased weight

Rare side effects (may affect up to 1 in 1000 people)

- Shingles (herpes zoster)
- Reduced number of white blood cells in the blood
- Reduced number of blood platelets
- Low calcium or sodium levels in the blood
- High level of blood fats
- Changes in mood, aggression, agitation, crying, stress symptoms, feeling confused (disorientation), early morning awakening, increased sex drive (increased libido), depressed mood, depression
- Fainting, memory impairment, disturbance in attention, dreamy state, uncomfortable sensation in legs (restless legs syndrome), poor quality sleep, tiredness (fatigue)
- Visual impairment, blurred vision, increased tearing
- A feeling of dizziness or spinning (Vertigo), dizziness when standing or sitting
- Faster heartbeats, chest pain due to angina pectoris
- Acid reflux, gastrointestinal disorder, blistering in the mouth, tongue ulceration, stomach upset, vomiting,
- abnormal bowel sounds, increased salivation, bad breath, flatulence, abdominal discomfort, inflammation of the stomach lining
- Abnormal dermal sensation (paresthesia), skin disorders (eczema, erythema, psoriasis, rash), nail disorder, sudden feeling of heat (hot flush)
- Pain, arthritis, muscle spasms, neck pain, night cramps,
- Passing large volumes of urine, presence of red blood cells in the urine, need to urinate at night
- Prolonged erection (priapism)
- Inflammation or swelling of prostate gland (prostatitis)
- Thirst
- Increased liver enzymes, abnormal blood electrolytes and abnormal laboratory tests

Not known (frequency cannot be estimated from available data)

- Spontaneous flow of milk from the chest

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Neomel Oral Solution

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 label after EXP. The expiry date refers to the last day of that month.

Store below 30°C

Do not store above 25°C after first opening of the bottle

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 Neomel Oral Solution contains

- Each 1 ml of Neomel Oral Solution contains 1 mg of the active substance melatonin.
- The other ingredients are purified water, sorbitol solution [Sorbitol (E420)], propylene glycol (E 1520), tri-sodium citrate (E331), hydroxyethyl cellulose (E1525), methyl hydroxybenzoate [Methyl parabens (E218)], propyl hydroxybenzoate [Propyl parabens (E216)].

What Neomel Oral Solution looks like and contents of the pack

Neomel is a clear, colorless, slightly viscous liquid.

It is supplied in a 160 ml amber PET plastic bottle with a polypropylene child-resistant, tamper-evident closure. A "press-in" LDPE bottle adapter and 5 ml polypropylene CE marked syringe dispenser with intermediate graduations of 0.5 ml is also provided in the carton.

Marketing Authorisation Holder

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