Package leaflet: Information for the user

Voquily 1 mg/ml oral solution
melatonin

Read all of this leaflet carefully before you or your child start using 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 (invented name) is and what it is used for

(Invented name) contains the active substance melatonin, which is a hormone produced naturally by the body. This hormone helps regulate the body's day- and night rhythm.

(Invented name) can be used for sleep onset insomnia in children and adolescents (6-17 years of age) with attention deficit hyperactivity disorder (ADHD) where other healthy sleeping routines have not worked well enough.

2. What you need to know before you take (invented name)

Do not take (invented name)
- 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 (invented name)
- if you have epilepsy. (Invented name) 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 (see section 3)
- if you have impaired liver function or kidney function
- if you smoke. Smoking may reduce the effect of (Invented name) as components of tobacco smoke can increase the breakdown of melatonin by the liver
- if you are elderly
- if you are a woman of childbearing potential. Contraceptives should be used during treatment with [invented name]. This medicinal product may however be affected by certain contraceptives, see the section 'Other medicines and {Invented name}' for more information.

Children below 6 years of age
Do not give this medicine to children below 6 years as its safety and efficacy are unknown.

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

- 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
- Smoking may decrease the effect of melatonin
- Carbamazepine (used in the treatment of epilepsy), as carbamazepine may decrease the effect of melatonin
- Beta-blockers (used to treat high blood pressure), as these medicines may reduce the effects of melatonin
- Nifedipine (used to treat high blood pressure), as melatonin may reduce the effect of nifedipine
- 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
- Thioridazine (used to treat mental/mood disorders), as both medicines taken together enhance feelings of drowsiness and difficulty in performing tasks
- Imipramine (used to treat depression), as both medicines taken together enhance feelings of drowsiness and difficulty in performing tasks
- Caffeine (stimulant), as melatonin interacts with caffeine.

(Invented name) with food, drink and alcohol

- Do not drink alcohol before, during or after taking (invented name), because of enhanced drowsiness when alcohol is taken with melatonin.

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.

<u>Contraceptives for fertile women and young girls</u>
Fertile women and young girls should use contraceptives when taking (Invented name). Because some contraceptives may increase melatonin levels in the body, the choice of contraceptive should be discussed with a doctor (see “Other medicines and (invented name)”).

<u>Pregnancy</u>
(Invented name) is not recommended if you or your child are pregnant. Melatonin crosses the placenta and there is insufficient information on the risk this may pose to the unborn child.

Breast-feeding
(Invented name) is not recommended if you or your child are breast-feeding. Melatonin passes into human milk, and a risk to the breast-fed child cannot be excluded.

Driving and using machines

(Invented name) 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.

(invented name) contains sorbitol and propylene glycol

This medicine contains 140 mg of sorbitol in each ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) 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 (or your child) take or receive this medicine.

This medicine contains 150 mg of propylene glycol in each ml.

3. How to take (invented name)

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

Recommended starting dose is 1-2 ml (1-2 mg) 30-60 minutes before bedtime.
The dose will be adjusted individually to a maximum of 5 ml (5 mg) daily, regardless of age. The lowest dose possible will be given.

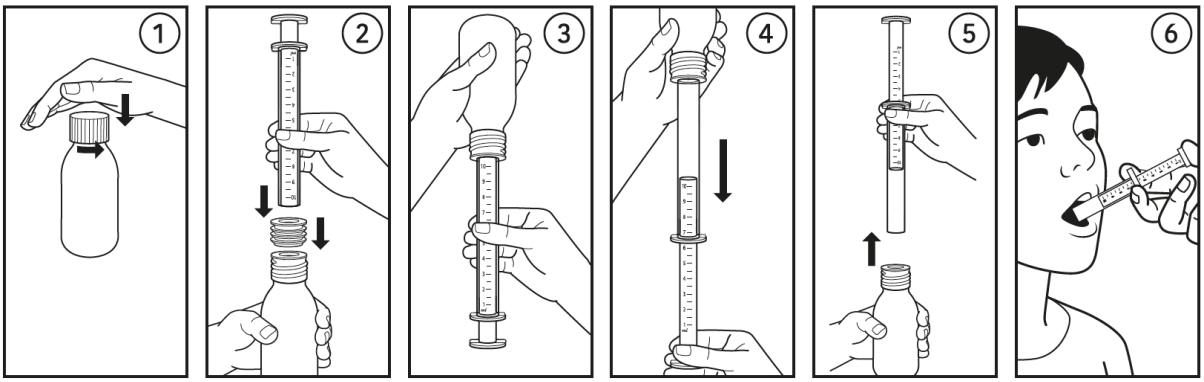
Treatment should be followed up regularly by a doctor (at least every 6 months is recommended) to see if it is still appropriate. Treatment should be interrupted once a year to see if treatment is still needed.

Diabetes
If you have or your child has diabetes or impaired glucose tolerance, food should not be consumed 2 hours before or 2 hours after intake of (invented name), see Warnings and precautions.

Directions for use
(Invented name) should be swallowed with a glass of water.
Food should not be consumed 1 hour before or 1 hour after intake of the medicine.

A 10 ml graduated oral syringe with intermediate graduations of 0.5 ml and a “press-in” bottle adapter are provided with the product.

- Open the bottle and at first use push the adapter into the opening of the bottle (1-2).
- Insert the syringe into the adapter (2-3) and invert the bottle.
- Draw out the required volume from the inverted bottle (4).
- Place the bottle in the upright position again and remove the filled syringe from the adaptor (5).
- Slowly push the contents of the syringe into the mouth and swallow the medicine (6).
- Clean the syringe and replace the cap to close the bottle (adapter remains in place).



If you take more (invented name) than you should
If you or your child has accidentally taken too much medicine, or if for example a child has ingested the medicine by mistake, contact a doctor or pharmacist as soon as possible.

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

If you forget to take (invented name)
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 in the morning.

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

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

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, or your child experience any of the following serious side effects, tell your doctor ***immediately*** and stop taking this medicine.

Frequency Not known
- Hypersensitivity reaction, (allergy like reactions such as itching, difficulty to breathe)
- Swelling of deeper layers of skin (angioedema)
- Swelling in mouth and tongue (oedema)

Other side effects that might occur are listed below.

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

Uncommon side effects (may affect up to 1 in 100 people)
- Irritability, nervousness, restlessness, insomnia
- Abnormal dreams, nightmares, night sweats, anxiety, anxious restlessness, physical weakness lack

of energy and enthusiasm
- Migraine
- Dizziness
- High blood pressure
- Abdominal pain, mouth ulceration, dry mouth, nausea
- Skin disorders (dermatitis, pruritus, rash, dry skin)
- Pain in arms and legs
- Menopausal symptoms
- Chest pain
- Excretion of glucose in the urine, excess protein 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 levels 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, increase 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), 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), swelling of the prostate (prostatitis)
- Thirst
- Increased liver enzymes, abnormal blood electrolytes, abnormal laboratory tests

Not known (frequency cannot be estimated from available data)
- Spontaneous flow of milk from the breasts (also in men)

Additional side effects in children and adolescents
A low frequency of generally mild side effects has been reported. The most common adverse effects were headache, hyperactivity, a feeling of dizziness or “spinning” (vertigo) and abdominal pain. No serious adverse effects have been observed.

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 in Appendix V.* By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store (invented name)

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 in the original carton in order to protect from light.
This medicine does not require any special temperature storage conditions

After first opening: use within 6 months.

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 (invented name) contains
- 1 ml contains 1 mg of melatonin.
- The other ingredients are:
  - Propylene glycol (E1520), sorbitol liquid (non crystallising) (E420), sucralose (E955), strawberry flavour (including propylene glycol (E1520)), purified water, hydrochloric acid (for pH adjustments) (E507).

What (invented name) looks like and contents of the pack
(Invented name) is a clear, colourless to yellowish solution with a smell of strawberry. The medicine is packed in an amber glass bottle, with a plastic child-resistant, tamper-evident screw cap. A plastic 10 ml oral syringe with intermediate graduations of 0.5 ml and a “press-in” syringe/bottle adaptor are also provided in each carton.

Pack size: 60 ml or 150 ml.

Not all packs may be marketed.

Marketing Authorisation Holder and Manufacturer
[To be completed nationally]

This leaflet was last revised in
2024-02-02