

Package leaflet: Information for the patient
Slenyto® 1mg prolonged-release tablets
(melatonin)

Your medicine is known as the above but will be referred to as Slenyto throughout the remainder of this leaflet. This product is available in other strengths.

Read all of this leaflet carefully before you or your child starts taking this medicine because it contains important information.

- 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 or your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours or your child's.
- If you or your child gets 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 Slenyto is and what it is used for
2. What you need to know before you or your child takes Slenyto
3. How to take Slenyto
4. Possible side effects
5. How to store Slenyto
6. Contents of the pack and other information

1. What Slenyto is and what it is used for

What Slenyto is

Slenyto is a medicine that contains the active ingredient, melatonin. Melatonin is a hormone produced naturally by the body.

What it is used for

Slenyto is used for treatment of **insomnia** (sleeplessness) in:

- **children and adolescents** (aged 2 to 18 years old) with **autism spectrum disorder (ASD)** and/or **neurogenetic diseases** (inherited conditions affecting the nerves and brain) associated with abnormal levels of melatonin and/or night-time awakenings, where other healthy sleeping routines (such as a regular bedtime and soothing sleeping environment) have not worked well enough.
- **children and adolescents** (aged 6 to 17 years old) with **attention-deficit hyperactivity disorder (ADHD)** where other healthy sleeping routines (such as a regular bedtime and soothing sleeping environment) have not worked well enough.

Slenyto shortens the time it takes to fall asleep and lengthens the duration of sleep. The medicine can help you or your child fall asleep and may help you or your child sleep for longer during the night.

2. What you need to know before you or your child takes Slenyto

DO NOT take Slenyto if you or your child

- is 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 Slenyto if you or your child:

- has liver or kidney problems. You should speak to your doctor before taking/giving Slenyto as its use is not recommended in such cases.
- suffers from an autoimmune disease (where the body's own immune (defence) system attacks parts of the body). You should speak to your doctor before taking/ giving Slenyto as its use is not recommended in such cases.

Slenyto may cause drowsiness and daytime fatigue. Caregivers should monitor the child for signs of daytime fatigue and contact their doctor for advice if symptoms occur. In particular, children and adolescents with ADHD may have increased daytime symptoms like inattention, hyperactivity, or behavioural disturbances.

Children

The safety and efficacy of Slenyto have not been established for children under 6 years of age with ADHD.

Do not give this medicine to children below the age of 2 years as it has not been tested and its effects are unknown.

Other medicines and Slenyto

Tell your doctor or pharmacist if you or your child is taking, has recently taken or might take any other medicines.

In particular, taking Slenyto with the following medicines can increase the risk of side effects, or it can affect the way that Slenyto or the other medicine works:

- **fluvoxamine** (used for the treatment of depression and obsessive compulsive disorder)
- **methoxypsoralens** (used in the treatment of skin disorders e.g. psoriasis)
- **cimetidine** (used in the treatment of stomach problems such as ulcers)
- **quinolones** (for example ciprofloxacin and norfloxacin) and **rifampicin** (used in the treatment of bacterial infections)
- **oestrogens** (used in contraceptives or hormone replacement therapy)
- **carbamazepine** (used in the treatment of epilepsy)
- **non-steroidal anti-inflammatory medicines** such as aspirin and ibuprofen (used for treating pain and inflammation). These medicines should be avoided, especially in the evening.
- **beta-blockers** (used to control blood pressure). These medicines should be taken in the morning.
- **benzodiazepines** and **non-benzodiazepine** hypnotics such as zaleplon, zolpidem and zopiclone (used to induce sleep)
- **thioridazine** (used for the treatment of schizophrenia)
- **imipramine** (used for the treatment of depression)

Smoking

Smoking can increase the breakdown of melatonin by the liver, which may make this medicine less effective.

Please tell your doctor if you or your child starts or stops smoking during treatment.

Slenyto with alcohol

Do not drink alcohol before, during or after taking Slenyto, because alcohol weakens the effect of the medicine.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Tell your doctor or pharmacist before using Slenyto if you or your daughter:

- is pregnant or might be pregnant. As a precautionary measure, it is preferable to avoid the use of melatonin during pregnancy.
- is breast-feeding or planning to breast-feed. It is possible that melatonin is passed into human breast milk, therefore your doctor will decide whether you or your daughter should breastfeed whilst taking melatonin.

Driving and using machines

Slenyto may cause drowsiness. After taking this medicine, you or your child should not drive a vehicle, ride a bicycle, or use machinery until completely recovered.

If you or your child suffers from continued drowsiness, you should consult your doctor.

Slenyto contains lactose

Slenyto contains lactose monohydrate. If you or your child has 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 Slenyto

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

Slenyto is available in two strengths:
1 mg and 5 mg.

Insomnia in children and adolescents (aged 2 to 18 years old) with ASD and/or neurogenetic diseases (inherited conditions affecting the nerves and brain) associated with abnormal levels of melatonin and/or night-time awakenings

The recommended starting dose is 2 mg (two 1-mg tablets) once daily. If there is no improvement in your/your child's symptoms, your doctor may increase the dose of Slenyto to find the most suitable dose for you/your child.

The maximum daily dose that you/your child will receive is 10 mg (two 5-mg tablets).

You or your child should be monitored by your doctor at regular intervals (recommended every 6months) to check that Slenyto is still the right treatment for you/them.