

**Package Leaflet:
Information for the user**

Slenyto® 1 mg
prolonged-release tablets
(melatonin)

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.

This product is called Slenyto 1 mg prolonged-release tablets but will be referred to as Slenyto throughout the leaflet.

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 6 months) to check that Slenyto is still the right treatment for you/them.

Insomnia in children and adolescents (aged 6 to 17 years old) with ADHD

The recommended starting dose is

1-2 mg (one to two 1-mg tablets) once daily. If there is no improvement in your/ your child's symptoms, the dose may be adjusted individually to 5 mg daily, regardless of age. If the doctor considers it necessary, the maximum daily dose may be increased to 10 mg (two 5-mg tablets) daily.

The lowest dose possible will be given, for the shortest possible time. You or your child should be monitored by your doctor at regular intervals (recommended every 6 months) to check that Slenyto is still the right treatment for you/them. Treatment should be interrupted once a year to see if treatment is still needed.

When to take Slenyto

Slenyto should be taken in the evening, 30 to 60 minutes before bedtime. The tablets should be taken after the evening meal, i.e. on a full stomach.

How to take Slenyto

Slenyto is for oral use. **The tablets should be swallowed whole and NOT broken, crushed or chewed.** Crushing and chewing damages the special properties of the tablet and means that they will not work properly.

The whole tablets can be put into food like yoghurt, orange juice or ice-cream to help with swallowing. If the tablets are mixed with these foods, they should be given immediately and not left or stored, as this may affect the way the tablets work. If the tablets are mixed with any other type of food, the tablets may not work properly.

If you or your child takes more Slenyto than you/they should

If you/your child has accidentally taken too much medicine, contact the doctor or pharmacist as soon as possible.

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

If you or your child forgets to take Slenyto

If you or your child forgets to take a tablet, it could be taken before going to sleep that night, but after this time, no other tablet should be taken before the next evening.

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

If you or your child stops taking Slenyto

You should talk to your doctor before you/your child stops taking Slenyto. It is important to continue taking this medicine to treat the condition.

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.

Unexpected changes in behaviour, such as aggression, may occur commonly (affecting between 1 in 100 to 1 in 10 people).

If this change in behaviour occurs, you must tell your doctor. The doctor may want you/your child to stop taking this medicine.

If any of the following side effects get serious or are troublesome, contact your doctor or seek medical advice:

Common: may affect between 1 in 100 to 1 in 10 people

- Changes in mood
- Aggression
- Irritability
- Drowsiness
- Headache
- Sudden onset of sleep
- Swelling and inflammation of the sinuses associated with pain and blocked nose (sinusitis)
- Tiredness
- Hangover feeling

Uncommon: may affect between 1 in 1000 to 1 in 100 people

- Depression
- Nightmares
- Agitation
- Stomach ache

Frequency not known (reported with another pharmaceutical form and strength)

- Fits (epilepsy)
- Visual impairment
- Breathlessness/shortness of breath (dyspnoea)
- Nose bleeds (epistaxis)
- Constipation
- Decreased appetite
- Swelling of the face
- Skin lesion
- Feeling abnormal
- Abnormal behaviour
- Low levels of white blood cells (neutropenia)

Reporting of side effects

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. You can also report side effects directly via the national reporting system.

For the United Kingdom:

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 Slenyto

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 30°C.

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.

If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6. Contents of the pack and other information

What Slenyto contains

1 mg strength

- The active substance is melatonin. Each tablet contains 1 mg melatonin.
- The other ingredients are ammonio methacrylate copolymer type B, calcium hydrogen phosphate dihydrate, lactose monohydrate, silica (colloidal anhydrous), talc, magnesium stearate, carmellose sodium (E466), maltodextrin, glucose monohydrate, lecithin (E322), titanium dioxide (E171), iron oxide red (E172) and iron oxide yellow (E172).

What Slenyto looks like and contents of the pack

1 mg strength

Slenyto 1 mg prolonged-release tablets are pink, film coated, round, biconvex, 3 mm diameter tablets.

Available in blister packs of 30 tablets.

Manufacturer

Iberfar Indústria Farmacêutica S.A.
Estrada Consiglieri Pedroso 123
Queluz de Baixo Barcarena
2734-501
Portugal

Procured from within the EU and repackaged for the PL Holder:

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For any information about this medicine, please contact the local representative of the Product Licence Holder:
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