

**Package Leaflet:  
Information for the user**



For children and adolescents aged 2-18

**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 for use in **children and adolescents** (2 to 18 years old) with **autism spectrum disorder (ASD)** and/or Smith-Magenis syndrome, a **neurogenetic disease** (inherited condition affecting the nerves and brain).

Slenyto shortens the time it takes to fall asleep and lengthens the duration of sleep. **It is for the treatment of insomnia (sleeplessness)** when a healthy sleeping routine (such as a regular bedtime and soothing sleeping environment) has not worked well enough. 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.
- feels drowsy (see section below on "Driving and using machines")

**Children under 2 years old**

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.

How much

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

When

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.

#### How long

Slenyto is for use in the treatment of insomnia. 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.

#### **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 from use in adults)

- 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](http://www.mhra.gov.uk/yellowcard) or search for

MHRA Yellow Card in the Google Play or Apple App Store.

For Ireland:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

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.

### **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).

##### 5 mg strength

- The active substance is melatonin. Each tablet contains 5 mg melatonin.
- The other ingredients are ammonio methacrylate copolymer type A, calcium hydrogen phosphate dihydrate, lactose monohydrate, silica (colloidal anhydrous), magnesium stearate, carmellose sodium (E466), maltodextrin, glucose monohydrate, lecithin (E322), titanium dioxide (E171) 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 / 60 tablets.

##### 5 mg strength

Slenyto 5 mg prolonged-release tablets are yellow, film coated, round, biconvex, 3 mm diameter tablets.

Available in blister packs of 30 tablets.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder**

RAD Neurim Pharmaceuticals EEC SARL

4 rue de Marivaux

75002 Paris

France

e-mail: [regulatory@neurim.com](mailto:regulatory@neurim.com)

#### **Manufacturer**

Iberfar - Indústria

Farmacêutica, S.A.

Rua Consiglieri Pedroso,

n.º 121-123 Queluz de Baixo

Barcarena

2734-501

Portugal

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

#### **Great Britain**

Flynn Pharma Limited

Tel: +44 (0) 1438 727822

e-mail:

[medinfo@flynnpharma.com](mailto:medinfo@flynnpharma.com)

#### **United Kingdom (Northern Ireland)/Ireland**

RAD Neurim Pharmaceuticals EEC SARL

Tel: +33 185149776 (FR)

e-mail: [neurim@neurim.com](mailto:neurim@neurim.com)

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#### **Other sources of information**

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>