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Slenyto (*melatonin*)

An overview of Slenyto and why it is authorised in the EU

What is Slenyto and what is it used for?

Slenyto is a medicine used to treat insomnia (difficulty sleeping) in:

- children and adolescents (2 to 18 years old) who have autism spectrum disorder (ASD), a range of conditions that affects a person's social interactions, and/or neurogenetic disorders (conditions caused by changes in genes that affect the functioning of the brain) associated with an abnormal production of melatonin or night awakenings, or both. Melatonin is a hormone that plays a key role in coordinating the body's sleep-wake cycle;
- children and adolescents (6 to 17 years old) who have attention-deficit hyperactivity disorder (ADHD).

Slenyto is used after other measures, such as keeping to a regular sleeping routine, have not worked.

The medicine contains the active substance melatonin.

How is Slenyto used?

Slenyto is available as prolonged-release tablets to be taken by mouth with or after food, 30 minutes to one hour before bedtime. Prolonged-release means that the active substance is released slowly over a few hours. The doctor should review treatment at least every 6 months and only continue treatment if the patient benefits from it.

The medicine can only be obtained with a prescription. For more information about using Slenyto, see the package leaflet or contact your doctor or pharmacist.

How does Slenyto work?

The active substance in Slenyto, melatonin, is a naturally occurring hormone, which is normally produced by a gland in the brain called the pineal gland. Melatonin is involved in coordinating the body's sleep cycle by acting on cells in specific areas of the brain and helping to bring about sleep. Its levels in the blood normally increase after the onset of darkness and peak in the middle of the night. Patients with certain conditions may produce less melatonin, leading to the development of insomnia.

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When given before bedtime, Slenyto increases levels of melatonin in the blood, helping these patients to sleep. Because Slenyto releases melatonin slowly over a few hours, it mimics the natural production of melatonin in the body.

What benefits of Slenyto have been shown in studies?

Autism spectrum disorder and neurogenetic disorders

Slenyto has been shown to be effective at improving sleeping time in children and adolescents with ASD and Smith-Magenis syndrome (a neurogenetic disorder associated with an abnormal production of melatonin).

A main study involved 125 patients from 2 to 17 years of age, including 121 with ASD and 4 with Smith-Magenis syndrome. All patients had previously tried other measures, such as keeping to a regular sleeping routine, which did not work. During the 13 weeks of treatment, patients given Slenyto slept on average 51 additional minutes per night compared with 19 additional minutes for those given placebo (a dummy treatment). In addition, children who took Slenyto fell asleep around 38 minutes earlier than usual while those taking placebo fell asleep 13 minutes earlier.

Data from the medical literature show that children and adolescents with neurogenetic disorders have problems with the production of melatonin, which can lead to sleep disturbances. Data also indicate that melatonin may improve the sleep pattern of these children when keeping to a regular sleeping routine did not work. It is therefore likely that the prolonged-release melatonin in Slenyto will help them with falling asleep and staying asleep.

Attention-deficit hyperactivity disorder

Slenyto has been shown to be effective at improving sleeping time in children and adolescents with ADHD.

In the study described above in patients with ASD, 36 children also had ADHD. Further analysis of the data showed that children with ADHD who took Slenyto slept on average about 33 minutes longer than those who received placebo. This improvement was mainly seen in children with ADHD who were 6 years old or above and was similar to that seen in children without ADHD who took Slenyto.

Supportive data from the medical literature also showed benefits of melatonin in improving sleep disturbances in children aged 6 years or older with ADHD.

What are the risks associated with Slenyto?

For the complete list of side effects and restrictions with Slenyto, see the package leaflet.

The most common side effects with Slenyto (which may affect up to 1 in 10 people) include sleepiness, tiredness, mood swings, headache, irritability, aggression and feeling hungover.

Why is Slenyto authorised in the EU?

The proportion of children with ASD, neurogenetic disorders and ADHD who also have insomnia is high and there are limited treatment options. Slenyto has been shown to increase the time patients with ASD and Smith-Magenis syndrome sleep and to reduce the time it takes for them to fall asleep. Data from the medical literature indicate that Slenyto is likely to be effective also in children with other neurogenetic disorders associated with an abnormal production of melatonin.

Slenyto is also expected to be effective in improving sleep disturbances in children aged 6 to 17 years with ADHD.

Concerning safety, the side effects with Slenyto are mild to moderate.

The European Medicines Agency therefore decided that Slenyto's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Slenyto?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Slenyto have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Slenyto are continuously monitored. Side effects reported with Slenyto are carefully evaluated and any necessary action taken to protect patients.

Other information about Slenyto

Slenyto received a marketing authorisation valid throughout the EU on 20 September 2018.

Further information on Slenyto can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/slenyto.

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