SLENYTO®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why do I or my child need SLENYTO?

- SLENYTO contains the active ingredient melatonin. SLENYTO is used for the treatment of insomnia in children and adolescents with autism spectrum disorder (ASD) and/or neurogenetic diseases, or attention-deficient hyperactivity disorder (ADHD). For more information, see Section 1. Why do I or my child need SLENYTO? in the full CMI.

2. What should I know before I or my child take SLENYTO?

Do not use if you or your child ever had an allergic reaction to SLENYTO or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you or your child has any other medical conditions, take any other medicines, if you are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before I or my child take SLENYTO? in the full CMI.

3. What if I or my child is taking other medicines?

Some medicines may interfere with SLENYTO and affect how it works. A list of these medicines is in Section 3. What if I or my child is taking other medicines? in the full CMI.

4. How do I or my child take SLENYTO?

- Your doctor will tell you what dose to take depending on your condition.
- SLENYTO is for oral use. Swallow your tablet whole with a full glass of water. If your child has difficulty swallowing tablets, the whole tablets can be put into food like yoghurt, orange juice or ice-cream to help with swallowing.

More instructions can be found in Section 4. How do I or my child take SLENYTO? in the full CMI.

5. What should I know while I or my child is taking SLENYTO?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you or your child is using SLENYTO. • If you become pregnant while taking SLENYTO, stop taking the tablets and tell your doctor immediately.
Things you should not do	• Do not crush, chew or divide your tablet. • Do not give SLENYTO to children under 2 years old. • Do not give SLENYTO to anyone else, even if they have the same condition as you. • Do not take more than the recommended dose unless your doctor tells you to. • Do not use this medicine to treat any other complaints unless your doctor tells you to.
Driving or 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.
Drinking alcohol	• Do not drink alcohol before or after taking this medicine.
Looking after your medicine	• Keep your tablets in the blister pack until it is time to take them. • Store below 30°C in a cool and dry place.

For more information, see Section 5. What should I know while I or my child is taking SLENYTO? in the full CMI.

6. Are there any side effects?

- Tell your doctor or pharmacist immediately if you notice any of the following side effects: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue, or other parts of the body, rash, itching or hives on the skin. They may be the signs of an allergic reaction. Common side effects include changes in mood, aggression, behavioural issues, irritability, drowsiness, headache, dizziness, stomach discomfort, sudden onset of sleep, swelling and inflammation of the sinuses associated with pain and blocked nose (sinusitis), tiredness, hangover feeling, bedwetting, rash, blood in stool, unusual emotions, repeating movements or gestures, restless, or being hyperactive and difficulty sleeping. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

SLENYTO®

Active ingredient: *melatonin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SLENYTO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SLENYTO.**

Where to find information in this leaflet:

1. Why do I or my child need SLENYTO?
2. What should I know before I or my child take SLENYTO?
3. What if I or my child is taking other medicines?
4. How do I or my child take SLENYTO?
5. What should I know while I or my child is taking SLENYTO?
6. Are there any side effects?
7. Product details

1. Why do I or my child need SLENYTO?

SLENYTO contains the active ingredient melatonin.

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 a neurogenetic diseases (inherited condition affecting the nerves and brain) associated with abnormal levels of melatonin and/or night awakenings
- children and adolescents (aged 6 to 17 years old) with attention-deficient hyperactivity disorder (ADHD)

Neurogenetic disorders are conditions that affect the brain, spinal cord, and nerves. They are caused by changes in genes that are passed down in families. These conditions can lead to a range of symptoms, such as developmental delays, learning difficulties, movement problems, or seizures.

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) have 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.

The active substance of SLENYTO, melatonin (not of plant or animal origin), belongs to a group of naturally occurring hormones produced in the body.

Melatonin works by controlling the circadian rhythms and increasing the propensity to sleep.

Your doctor, however, may prescribe SLENYTO for another purpose.

Ask your doctor if you have any questions about why this medicine has been prescribed for you or your child.

SLENYTO is not addictive.

2. What should I know before I or my child take SLENYTO?

Warnings

Do not use SLENYTO if:

- you or your child are allergic to melatonin, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
  - shortness of breath
  - wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body
  - rash, itching or hives on the skin
- Always check the ingredients to make sure you or your child can use this medicine.

Do not give SLENYTO to children under 2 years old.

Check with your doctor if you or your child have had any of the following medical conditions:

- liver or kidney problems.
  You should speak to your doctor before taking/giving SLENYTO as its use is not recommended in such cases.
- 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.
- an intolerance to some sugars, contact your doctor before taking this medicinal product because SLENYTO contains lactose monohydrate.
- been feeling drowsy

During treatment, you or your child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you or your daughter are pregnant or intend to become pregnant.

As a precautionary measure, it is preferable to avoid the use of melatonin during pregnancy.

Talk to your doctor if you or your daughter are breastfeeding or intend to breastfeed.

It is possible that melatonin is passed into human breast milk, therefore your doctor will decide whether your daughter should breastfeed whilst taking melatonin.

3. What if I or my child is taking other medicines?

Tell your doctor or pharmacist if you or your child is taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and SLENYTO may interfere with each other. These include:

- 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)

The effect of adding SLENYTO to other medicines used to treat insomnia has not been examined. It is not known if SLENYTO will increase or decrease the effects of other treatments for insomnia.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you or your child is taking and if these affect SLENYTO.

4. How do I or my child take SLENYTO?

How much to take

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

For treatment of insomnia for autism spectrum disorder and/or a neurogenetic diseases (inherited condition affecting the nerves and brain) associated with abnormal levels of melatonin and/or night awakenings:

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

For treatment of insomnia for attention-deficient hyperactivity disorder (ADHD):

- The recommended starting dose is 1-2 mg (one to two 1 mg tablets) once daily. If there is no improvement in you/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).

How to take it

- SLENYTO is for oral use. Swallow your tablet whole with a full glass of water.
- **Do not crush, chew or divide your tablet.** Each SLENYTO tablet has been specially designed to release the right dose of medicine while you sleep. If you crush, chew or divide the tablet it will not work properly.
- If your child has difficulty swallowing tablets, 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.
- Follow the instructions provided and use SLENYTO until your doctor tells you to stop.

When to take it

- SLENYTO should be taken in the evening, 30 to 60 minutes before bedtime. The tablets should be taken with or after food, i.e. on a full stomach.

How long to take it

It is important that you continue taking SLENYTO for as long as your doctor prescribes.

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

If you or your child forget to use SLENYTO

SLENYTO should be used regularly at the same time each day. 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 the dose you missed.

If you have trouble remembering to take SLENYTO, ask your pharmacist for some hints.

If you or your child use too much SLENYTO

If you think that you or your child has used too much SLENYTO, you or your child may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia and in New Zealand 0800 POISON [0800 764 766]),** or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while I or my child is taking SLENYTO?

Things you should do

- If you or your child is about to be started on any new medicine tell your doctor and pharmacist that you or your child is taking SLENYTO.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.
- If you become pregnant while taking SLENYTO, stop taking the tablets and tell your doctor immediately.

Call your doctor straight away if you or your child:

- suffers from continued drowsiness

Remind any doctor, dentist or pharmacist you visit that you or your child is using SLENYTO.

Things you should not do

- Do not give SLENYTO to anyone else, even if they have the same condition as you.
- Do not take more than the recommended dose unless your doctor tells you to.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not give SLENYTO to children under 2 years old. There is no experience with its use in children under 2 years old.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SLENYTO affects you.

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.

Drinking alcohol

Do not drink alcohol when taking this medicine.

Alcohol weakens the effect of the medicine.

Smoking

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

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

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep as well.
- Keep the medicine in a place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you or your child do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Head and neurology related: • changes in mood • aggression • behavioural issues • irritability • drowsiness • headache • dizziness • sudden onset of sleeptiredness • hangover feeling • agitation • nightmares • depression • difficulty sleeping Restlessness or being hyperactive • repeating movements or gestures • unusual emotions • panic attacks • phobias **Allergy related:** • swelling and inflammation of the sinuses associated with pain and blocked nose (sinusitis) **Gastrointestinal related:** • constipation • decreased appetite • stomach ache/discomfort • vomiting • nausea • increased appetite • dry mouth • bad breath **Skin related:** • rash	**Speak to your doctor if you or your child have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Eyes related: • visual impairment **Allergy related:** • breathlessness/shortness of breath (dyspnoea) • swelling of the face **Blood related:** • nose bleeds (epistaxis) • low levels of white blood cells (neutropenia) **Head and neurology related:** • fits (epilepsy) • feeling abnormal • abnormal behaviour **Skin related:** • skin lesion **Heart related:** • Fast or irregular heartbeat **Gastrointestinal related:** • blood in the stool	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you or your child feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you or your child experiences, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines or stop giving any medicines to your child.

7. Product details

This medicine is only available with a doctor's prescription.

What SLENYTO contains

Active ingredient (main ingredient)	SLENYTO 1 mg prolonged release tablets contain 1 mg melatonin SLENYTO 5 mg prolonged release tablets contain 5 mg melatonin
Other ingredients (inactive ingredients)	SLENYTO 1 mg prolonged release tablet:

	• ammonio methacrylate copolymer • calcium hydrogen phosphate dihydrate • lactose monohydrate • colloidal anhydrous silica • purified talc • magnesium stearate • Opaglos 2 High Gloss Film Coating System 97W240002 Pink (film coating) SLENYTO 5 mg prolonged release tablet: • ammonio methacrylate copolymer • calcium hydrogen phosphate dihydrate • lactose monohydrate • colloidal anhydrous silica • magnesium stearate • Opaglos 2 High Gloss Film Coating System 97W220004 Yellow (film coating)
Potential allergens	No

Do not take this medicine if you or your child is allergic to any of these ingredients.

What SLENYTO looks like

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

Available blister packs of 30 / 60 tablets.

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

Available in blister packs of 30 tablets.

Australian Registration Number:

1 mg tablets AUST R: 319503

5 mg tablets AUST R: 319504

Who distributes SLENYTO

Distributed in Australia by:

Aspen Pharmacare Australia Pty Ltd

34-36 Chandos Street

St Leonards NSW 2065

Distributed in New Zealand by:

Pharmacy Retailing t/a

Healthcare Logistics

58 Richard Pearse Drive

Airport Oaks

Mangere

Auckland

Ph: +64 9 915 9500

This leaflet was prepared in May 2026.