

Product Name	Ceyesto 1 micrograms/ml Oral Solution
MA Number	PL 44490/0001
Component	Patient Leaflet (oral solution)
Artwork Number	PL-MEL-OS-1-REV 03

FRONT

PACKAGE LEAFLET: INFORMATION FOR THE USER

CEYESTO® 1 mg/ml Oral Solution Melatonin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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.
- If you get 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 Ceyesto is and what it is used for
2. What you need to know before you take Ceyesto
3. How to take Ceyesto
4. Possible side effects
5. How to store Ceyesto
6. Contents of the pack and other information

1. What Ceyesto is and what it is used for

The active substance of Ceyesto, melatonin, belongs to a natural group of hormones produced by the body. The hormone helps regulate the body's day and night rhythm.

Ceyesto is used for:

- Treatment of delayed sleep wake phase disorder (DSWPD) (disruption of the body's day and night rhythm) in children and adolescents (6 to 17 years old) and adults up to 25 years of age, where healthy sleeping routines have not worked well enough.
- Short-term treatment of jet lag in adults. Jet lag refers to the symptoms caused by the time difference when travelling through several time zones.
- Insomnia (sleeplessness) in children and adolescents (6 to 17 years old) with ADHD, where healthy sleeping routines have not worked well enough.
- Sedation of children and adolescents (1 to 18 years old) who are having a medical procedure called an electroencephalogram (EEG) in hospital.

2. What you need to know before you take Ceyesto

Do not take Ceyesto:

- if you are 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 Ceyesto if you suffer from:

- **diabetes or impaired glucose tolerance**, as this medicine may increase the level of glucose in your blood
- **epilepsy**
- **an autoimmune disease** (where the body is 'attacked' by its own immune system)
- **liver or kidney problems**

Smoking may make Ceyesto less effective, because the components of tobacco smoke can increase the breakdown of melatonin by the liver.

Other medicines and Ceyesto

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may **increase** the effect of melatonin. These include:

- **Fluvoxamine** (used for the treatment of depression and obsessive compulsive disorder)
- **Psoralens** (used in the treatment of skin disorders such as psoriasis)
- **Cimetidine** (used for the treatment of stomach problems such as ulcers)
- **Oestrogens** (used in contraceptives or hormone replacement preparations)
- **Quinolones** (used in the treatment of bacterial infections)

Some medicines may **decrease** the effect of melatonin. These include:

- **Rifampicin** (used in the treatment of bacterial infections)
- **Carbamazepine** (used in the treatment of epilepsy)

Melatonin can **increase the sedative effect** of some medicines:

- **Benzodiazepines and non-benzodiazepine hypnotics** (medicines used to induce sleep such as midazolam, temazepam, zolpidem, zopiclone). Melatonin may enhance certain side effects of zolpidem (morning sleepiness, nausea, confusion).

Melatonin may **influence the effect** of:

- **Warfarin** (an anticoagulant, used to prevent blood clotting)

Ceyesto with food, drink and alcohol

Food may alter the effectiveness of Ceyesto. Do not eat food 2 hours before or after taking melatonin.

Do not drink alcohol while taking Ceyesto because it may reduce the effect of melatonin on sleep and can potentially worsen certain symptoms of sleep related conditions e.g. headache, morning fatigue and impaired concentration.

Pregnancy, breast-feeding and fertility

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

- **Pregnancy**

Ceyesto is not recommended if you are pregnant. Melatonin crosses the placenta and there is not enough information on the risk this may pose to the unborn child.

- **Breast-feeding**

Ceyesto is not recommended if you are breast-feeding. Melatonin is excreted in human milk, and a risk to the suckling child cannot be excluded.

- **Fertility**

Ceyesto is not recommended in women or men planning to have a baby as there is insufficient information on the effects of melatonin on fertility.

- **Women of childbearing potential**

You must use contraception when taking melatonin if you are a woman of childbearing potential.

Driving and using machines

Do not drive or operate machinery just after you have taken melatonin. Melatonin may cause drowsiness. Alertness may be affected for several hours after taking melatonin.

Important information about some of the ingredients of Ceyesto

This medicine contains 6 mg benzyl alcohol in each ml. Benzyl alcohol may cause allergic reactions.

Do not take Ceyesto if you are allergic to benzyl alcohol.

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called 'gaspings syndrome') in young children. Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor. Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

Ask your doctor or pharmacist for advice if you are pregnant, breast-feeding or have liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called 'metabolic acidosis').

This medicine contains 52 mg propylene glycol (E 1520) in each ml.

If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

3. How to take Ceyesto

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

Short-term treatment of jet lag (sleep disorder after a long flight)

The recommended dose is:

3 to 6 mg (3 to 6 ml) of Ceyesto before going to bed for 3 to 4 days after your flight.

Timing of the dose is important, because if taken at the wrong time, Ceyesto may cause sleepiness and delay adapting to local time. Ceyesto should not be taken before 8 pm at night or after 4 am in the morning.

Consult a doctor if the symptoms do not improve within 6 days or if they get worse.

Delayed sleep wake phase disorder

The recommended dose is:

1 to 5 mg (1 to 5 ml) per day, 1 to 2 hours before going to bed. **The maximum daily dose is 5 mg (5 ml)**. Your doctor will likely start you at a low dose (1 to 2 mg) and adjust it depending on your response.

Insomnia (sleeplessness) in children and adolescents with ADHD

In children and adolescents with ADHD, the recommended starting dose is 1 to 2 mg (1 to 2 ml), 30 to 60 minutes before bedtime. The dose can be increased up to a **maximum of 5 mg (5 ml)** per day depending on your response.

For both insomnia and DSWPD, you or your child should be monitored by your doctor at regular intervals (recommended at least every 6 months) to check that Ceyesto is still the right treatment for you/them. Treatment should be interrupted once a year to see if it is still needed. For some patients, treatment can be continued past the usual age ranges if the doctor considers it appropriate.

Sedation

Ceyesto will be given 30 to 45 minutes before the start of the procedure. The dose will be determined by your doctor depending on your child's weight. A 'top-up' dose may be given if sleep is not achieved 45 minutes after the first dose – this will usually be half the first dose. Only one melatonin assisted EEG should be performed per 24 hour period.

Method of administration

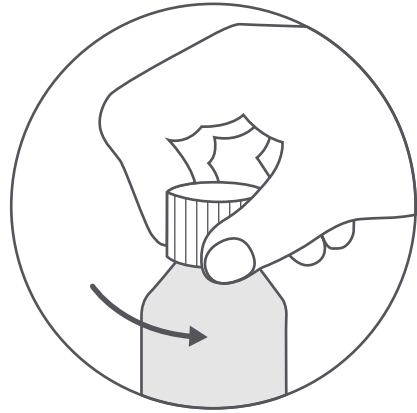
Do not eat food 2 hours before or after taking Ceyesto.

Ceyesto Oral Solution is for oral use only. A 5 ml oral syringe graduated every 0.5 ml from 0.5 ml to 5 ml is provided.

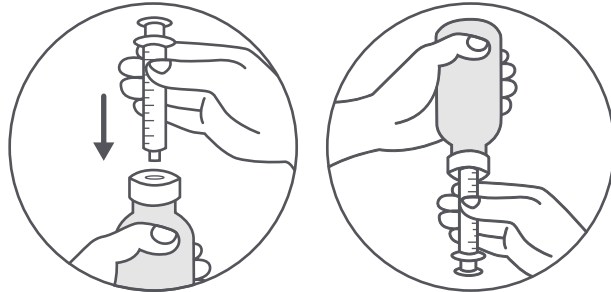
BACK

Instructions for use

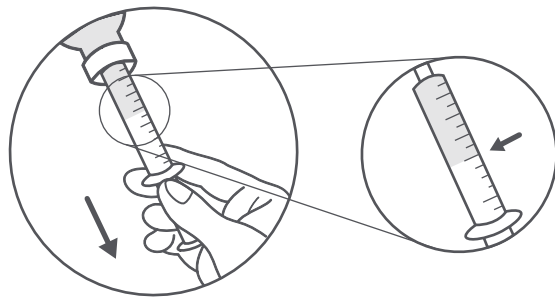
1. Open the bottle; on first opening the seal is broken.



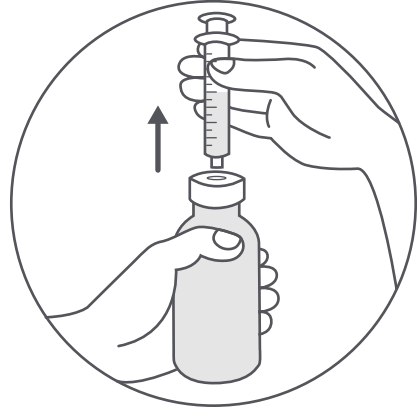
2. Check the syringe adaptor is already securely in place.
3. Insert the oral syringe firmly into the adaptor and turn the bottle upside down. This will allow you to fill the syringe with the dose that needs to be administered.



4. Holding the bottle, slowly draw out the plunger until you reach the marking for the prescribed dose.



5. Turn the bottle up the correct way and carefully take the syringe out of the bottle.



6. You or your child should sit upright when taking the medicine. Place the tip of the syringe into your (or your child's) mouth and slowly push the plunger down to release the dose into your / their mouth.



7. Repeat steps 3 - 6 if doses greater than 5 ml are required.
8. Rinse the syringe with water after each use and replace the cap on the bottle. Replace the bottle in the carton.

If you take more Ceyesto than you should

If you have taken more Ceyesto than recommended and you do not feel well, please contact your doctor, hospital or pharmacy.

The most common symptoms of overdose are drowsiness, headache, dizziness and nausea.

If you forget to take Ceyesto

Do not take a double dose to make up for a forgotten dose. Simply take your next dose at the correct time.

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.

Immediately stop taking the medicine and contact a doctor if you experience any of the following serious side effects:

- Hypersensitivity reaction, swelling of face, mouth and / or tongue

The following side effects have also been reported:

Common side effects: may affect up to 1 in 10 people

- Headache
- Sleepiness

Uncommon side effects: may affect up to 1 in 100 people

- Irritability, nervousness, restlessness, abnormal dreams, anxiety
- Dizziness
- High blood pressure
- Abdominal pain, indigestion, mouth ulcers, dry mouth, feeling sick
- Itching, rash, dry skin
- Excess proteins in your urine
- Too much sugar in your urine
- Feeling of weakness, chest pain
- Abnormal liver function tests
- Weight gain

Rare side effects: may affect up to 1 in 1000 people

- Reduced number of white blood cells and blood platelets in blood tests
- High level of blood fats (triglycerides)
- Altered mood, aggression, disorientation, increased sex drive
- Fainting, memory impairment, restless legs syndrome, 'pins and needles' feeling
- Visual impairment, blurred vision, watery eyes
- Vertigo
- Feeling your heartbeat
- Hot flushes
- Vomiting, wind, excess saliva production, bad breath, inflammation of the stomach lining
- Nail disorder
- Arthritis, muscle spasms
- Passing large volumes of urine
- Presence of red blood cells in the urine
- Prolonged erection without sexual stimulation (possibly painful)
- Inflammation of the prostate gland
- Thirst
- Abnormal blood electrolytes

Frequency not known: cannot be estimated from the available data

- Hypersensitivity reaction, swelling of mouth and tongue
- Abnormal milk secretion
- High blood sugar

Reporting of side effects

If you get 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 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 Ceyesto

Keep the bottle in the outer carton in order to protect from light. Store below 25°C.

After first opening store below 25°C and use within 1 month.

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 label or carton (EXP). The expiry date refers to the last day of that month.

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 protect the environment. Recycle the empty packaging where possible.

6. Contents of the pack and other information

What Ceyesto contains

The active substance is melatonin. Each 1 ml of Ceyesto contains 1 mg of melatonin.

The other ingredients are purified water, sucralose, benzyl alcohol, sodium ascorbate, propylene glycol (E 1520) and strawberry flavour.

What Ceyesto looks like and contents of the pack

Ceyesto is a clear, colourless to yellowish solution with a characteristic strawberry odour.

It is supplied in 100 ml, 150 ml or 200 ml amber, type III glass bottles with a white polypropylene (PP) / polyethylene (PE) tamper-evident, child-resistant screw cap with a PE syringe adaptor insert and a plastic 5 ml oral syringe (graduated every 0.5 ml from 0.5 to 5 ml). Not all pack sizes may be marketed.

Marketing Authorisation Holder:

ALTURIX Ltd
287 Upper Fourth Street
Milton Keynes
MK9 1EH

Manufacturer:

One Pharma Industrial Company SA
60th km N.N.R. Athinon-Lamias
Sximatari Voiotias, 32009
Greece

This leaflet was last revised in December 2023.