

Product Name	CEYESTO 3mg Tablets
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PACKAGE LEAFLET: INFORMATION FOR THE USER

CEYESTO 3 mg tablets

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 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.

Ceyesto is used for:

- 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 – travelling east or west.
- Insomnia in children and adolescents (6 to 17 years old) with ADHD, where other healthy sleeping routines have not worked well enough.

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:

- **Epilepsy.** Ceyesto may increase seizure frequency in patients with epilepsy.
- **Renal impairment.** The use of Ceyesto if you have kidney disease is not recommended.
- **Hepatic impairment.** The use of Ceyesto if you have liver disease is not recommended.
- **Autoimmune disease** (where the body is 'attacked' by its own immune system). The use of melatonin in this case is not recommended.
- **A cardiovascular condition** for which you use antihypertensive medication. The use of melatonin in this case is not recommended.

The timing of the melatonin dosing is important. Ceyesto should be used as instructed.

Ceyesto can make you feel drowsy. You should be careful if the drowsiness affects you as it may impair your ability on tasks such as driving.

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

Children and adolescents

Ceyesto should not be given to children and adolescents under 18 years old for the treatment of jet lag.

Ceyesto should not be given to children below the age of 6 years with ADHD.

The safety profile of melatonin especially in long-term use is not fully established. Long-term melatonin use may negatively affect blood glucose control, pubertal development and sexual maturation.

Other medicines and Ceyesto

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

- **Fluvoxamine** (used for the treatment of depression and obsessive compulsive disorder),
- **Quinolones and rifampicin** (used in the treatment of bacterial infections), oestrogens (used in contraceptive or hormone replacement therapy), carbamazepine (used in the treatment of epilepsy) and 5- or 8-methoxypsoralen (5 and 8-MOP) (used in the treatment of skin diseases such as psoriasis).

- **Adrenergic agonists/antagonists** (such as certain types of medicines used to control blood pressure by constricting blood vessels, nasal decongestants, blood pressure lowering medicines), opioid agonists /antagonists (such medicinal products used in the treatment of drug addiction), prostaglandin inhibitors (such as nonsteroidal anti-inflammatory medicines), antidepressant medication, tryptophan and alcohol.
- **Cimetidine** (used for the treatment of stomach problems such as ulcers), calcium channel blockers (medicines used to treat high blood pressure and sudden chest pain [angina pectoris], such as nifedipine).
- **Benzodiazepines and non-benzodiazepine hypnotics** (medicines used to induce sleep such as zaleplon, zolpidem and zopiclone).
- **Thioridazine** (for the treatment of schizophrenia) and imipramine (for the treatment of depression).
- **Warfarin and other anticoagulants**, e.g. dabigatran, rivaroxaban, apixaban, edoxaban (used to prevent blood clotting) – INR may be necessary to verify more specifically.

Ceyesto with food, drink and alcohol

Food may alter the effectiveness of Ceyesto. It is recommended that food is not consumed 2 hours before or 2 hours after the scheduled time of melatonin intake. Do not drink alcohol before, during or after taking Ceyesto, because it reduces the effectiveness of Ceyesto and it can potentially worsen certain symptoms of jet-lag (e.g. headache, morning fatigue, impaired concentration).

Pregnancy and breast-feeding

The use of Ceyesto during pregnancy is not recommended. Ceyesto should not be used if you are breast-feeding.

Driving and using machines

Ceyesto has moderate influence on the ability to drive and use machines. Melatonin may cause drowsiness. Alertness may be affected for several hours after taking melatonin. Do not drive or operate machinery after you have taken melatonin.

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.

Tablets should be swallowed with a glass of water. It is recommended that food is not consumed within 2 hours before or 2 hours after the scheduled time of melatonin intake.

Jet lag in adults

The recommended dose is one 3 mg tablet daily for a maximum of 4 days. The first dose should be taken on arrival at your destination at your usual bedtime (local time). The dose on the following days should also be at your usual bedtime. Other dosages from other manufacturers are available to achieve higher than 3 mg dose if required.

Timing of melatonin is important, because if taken at the wrong time, melatonin may cause sleepiness and delay adaptation to local time. Therefore, the tablets should not be taken before 20:00 hr or after 04:00 hr.

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

Children and adolescents

Do not give this medicine to children and adolescents under 18 years of age as the safety and efficacy of melatonin in the treatment of jet lag has not been established.

Insomnia in children and adolescents aged 6–17 years with ADHD

Your doctor will decide the starting dose and if needed will increase the dose of melatonin to find the most suitable dose for you/your child. The tablet is taken 30–60 minutes before bedtime. The maximum daily dose that you/your child will receive is 3 mg. Ceyesto is suitable only when the lowest effective dose has been established by your doctor to be 3 mg.

Your doctor should evaluate the treatment effect at regular intervals and consider stopping treatment if no clinically relevant treatment effect is seen.

Children below 6 years of age

Ceyesto tablets are not recommended for children below 6 years with ADHD. The safety and efficacy of melatonin in children less than 6 years has not been established.

If you take more Ceyesto than you should

If you have taken too much of your medicine or if a child has accidentally taken this medicine, always contact a doctor or hospital to assess the risks and to get additional instructions. Taking more than the recommended daily dose may make you feel drowsy.

If you forget to take Ceyesto

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

If you stop taking Ceyesto

There are no known harmful effects if treatment is interrupted or ended early. The use of Ceyesto is not known to cause any withdrawal effects after treatment completion.

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.

The most frequently reported side effects in short-term use for jet lag in adults are headache, nausea, loss of appetite, dizziness, daytime sleepiness and disorientation.

In prolonged use, the most frequently reported side effects are drowsiness, headache, dizziness, and nausea.

In children and adolescents, the most common side effects reported are headache, hyperactivity, dizziness and abdominal pain. Long term effects are poorly known.

When used for other disorders melatonin has been reported to cause a spectrum of adverse effects.

If you experience any of the following **serious side effects**, stop taking the medicine and contact your doctor **immediately**.

Uncommon: (*may affect up to 1 in 100 people*)

- Chest pain

Rare: (*may affect up to 1 in 1000 people*)

- Loss of consciousness or fainting
- Severe chest pain due to angina
- Feeling your heartbeat
- Depression
- Visual impairment
- Disorientation
- Vertigo (a feeling of dizziness or "spinning")
- Presence of blood in the urine
- Reduced number of white blood cells in the blood
- Reduced blood platelets, which increases risk of bleeding or bruising
- Psoriasis

Frequency not known: (*cannot be estimated from the available data*)

- Hypersensitivity reaction
- Swelling of the skin

If you experience any of the following non-serious side effects contact your doctor and/ or seek medical advice:

Uncommon: (*may affect up to 1 in 100 people*)

- Irritability
- Nervousness
- Restlessness
- Insomnia
- Abnormal dreams
- Nightmares
- Anxiety
- Migraine
- Headache
- Lethargy (tiredness, lack of energy)
- Restlessness associated with increased activity
- Dizziness
- Tiredness
- High blood pressure
- Abdominal pain
- Indigestion
- Mouth ulceration
- Dry mouth
- Nausea
- Changes in the composition of your blood which could cause yellowing of the skin or eyes
- Inflammation of the skin
- Night sweats
- Itching
- Rash
- Dry skin
- Pain in extremities
- Excretion of glucose in the urine
- Excess proteins in the urine
- Menopausal symptoms
- Feeling of weakness
- Abnormal liver function
- Weight increase

Rare: (*may affect up to 1 in 1000 people*)

- Shingles
- High level of fatty molecules in the blood
- Altered mood
- Aggression
- Agitation
- Crying
- Stress symptoms
- Early morning awakening
- Increased sex drive
- Depressed mood
- Memory impairment
- Disturbance in attention
- Dreamy state
- Restless legs syndrome
- Poor quality sleep
- 'Pins and needles' feeling
- Watery eyes
- Dizziness when standing or sitting
- Hot flushes
- Acid reflux

- Stomach disorder
- Blistering in mouth
- Tongue ulceration
- Stomach upset
- Vomiting
- Abnormal bowel sounds
- Wind
- Excess saliva production
- Bad breath
- Abdominal discomfort
- Gastric disorder
- Inflammation of the stomach lining
- Eczema
- Skin rash
- Hand dermatitis
- Itchy rash
- Nail disorder
- Arthritis
- Muscle spasms
- Neck pain
- Night cramps
- Passing large volumes of urine
- Urinating during the night
- Prolonged erection that might be painful
- Inflammation of the prostate gland
- Tiredness
- Pain
- Thirst
- Increased liver enzymes
- Abnormal blood electrolytes
- Abnormal laboratory tests

Frequency not known: (*cannot be established from the available data*)

Swelling of mouth or tongue, and abnormal milk secretion.

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 Yellow Card Scheme, Website: www.mhra.gov.uk/yellow-card 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 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.

Store in the original package in order to protect from light.

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.

6. Contents of the pack and other information

What Ceyesto contains

The active substance is melatonin.

Each 3 mg tablet contains 3 mg of melatonin.

The other ingredients are:

Calcium hydrogen phosphate dihydrate, Microcrystalline cellulose, Magnesium stearate, Silica colloidal anhydrous and Starch pregelatinised.

What Ceyesto looks like and contents of the pack

White, round, convex tablet with logo 7, diameter 7 mm.

10, 30 and 50 tablets in blister packs (PVC/Al) or in tablet container (container HD-PE plastic and closure LD-PE plastic)

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

ALTURIX Limited
287 Upper Fourth Street
Milton Keynes
MK9 1EH
United Kingdom

Manufacturer

Vitalbans Oy
Varastokatu 7-9
13500 Hämeenlinna
Finland

This medicinal product is authorised in the Member States of the EEA under the following names:

Ceyesta: Finland

Ceyesto: United Kingdom

This leaflet was last revised in 11.2022