Package leaflet: Information for the patient

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.

Your medicine is available as the above name but will be referred to as Ceyesto throughout this leaflet.

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 Ceyesto in this case is not recommended.
- **A cardiovascular condition** for which you use antihypertensive medication. The use of Ceyesto in this case is not recommended.

The timing of the Ceyesto 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 Ceyesto 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 Ceyesto especially in long-term use is not fully established. Long-term Ceyesto 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 contraceptives 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 Ceyesto 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. Ceyesto may cause drowsiness.

Alertness may be affected for several hours after taking Ceyesto.

Do not drive or operate machinery after you have taken Ceyesto.

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 Ceyesto 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 Ceyesto is important, because if taken at the wrong time, Ceyesto 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 Ceyesto 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 Ceyesto 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 Ceyesto 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 Ceyesto 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
- 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

- High blood pressure
- Abdominal pain
- Indigestion
- Mouth ulceration
- 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
- 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
- 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
- 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/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 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.

If your medicine shows visible signs of deterioration, show it to a pharmacist who will advise you what to do.

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 tablet contains 3 mg 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
Ceyesto is white, round, convex tablet with logo 7 imprinted on one side and plain on reverse with diameter of 7 mm.

Your medicine is available in blister packs of 30 tablets.

Manufacturer:
Vitabalans Oy, Varastokatu 7-9, 13500 Hämeenlinna, Finland.

Procured from within the EU by the Product Licence Holder:
Quantum Pharmaceutical, Quantum House, Hobson Industrial Estate, Burnopfield, Co. Durham, NE16 6EA.

Repackaged by:
UAB Actiofarma, Kaunas, Lithuania.

Ceyesto 3 mg tablets POM

PL: 21923/0188

Blind or partially sighted?
Is this leaflet hard to see or read?
Call +44 (0)1207 279 400
to obtain the leaflet in a format suitable for you.

This leaflet was last revised on 11 Sep 2025.

Ceyesto® is a registered trademark of Alturix Limited.

Package leaflet: Information for the patient

Melatonin 3 mg tablets

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

Your medicine is available as the above name but will be referred to as Melatonin throughout this leaflet.

What is in this leaflet

1. What Melatonin is and what it is used for
2. What you need to know before you take Melatonin
3. How to take Melatonin
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6. Contents of the pack and other information

1. What Melatonin is and what it is used for

The active substance of Melatonin, melatonin, belongs to a natural group of hormones produced by the body.

Melatonin 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 Melatonin

Do not take Melatonin:
- 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 Melatonin, if you suffer from:
- **Epilepsy.** Melatonin may increase seizure frequency in patients with epilepsy.
- **Renal impairment.** The use of Melatonin if you have kidney disease is not recommended.
- **Hepatic impairment.** The use of Melatonin 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. Melatonin should be used as instructed.

Melatonin 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 Melatonin less effective, because the components of tobacco smoke can increase the breakdown of melatonin by the liver.

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

Melatonin 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 Melatonin
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 contraceptives 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.

Melatonin with food, drink and alcohol
Food may alter the effectiveness of Melatonin. 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 Melatonin, because it reduces the effectiveness of Melatonin and it can potentially worsen certain symptoms of jet-lag (e.g. headache, morning fatigue, impaired concentration).

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

Driving and using machines
Melatonin 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 Melatonin

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

If you stop taking Melatonin
There are no known harmful effects if treatment is interrupted or ended early. The use of Melatonin 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
- 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

- High blood pressure
- Abdominal pain
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- Menopausal symptoms
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- Shingles
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