

Package leaflet: Information for the patient

Melatonin Italfarmaco 0.5 mg tablets

Melatonin Italfarmaco 1 mg tablets

Melatonin Italfarmaco 2 mg tablets

Melatonin Italfarmaco 3 mg tablets

Melatonin Italfarmaco 4 mg tablets

Melatonin Italfarmaco 5 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, pharmacist, or nurse.
- 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, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Name of the medicinal product] is and what it is used for
2. What you need to know before you take [Name of the medicinal product]
3. How to take [Name of the medicinal product]
4. Possible side effects
5. How to store [Name of the medicinal product]
6. Contents of the pack and other information

1. What [Name of the medicinal product] is and what it is used for

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

[Name of the medicinal product] is used for:

- short-term treatment of jet lag in adults. Jet lag refers to the symptoms caused by the time difference when traveling across several time zones.
- sleep onset insomnia in children and adolescents (6 to 17 years old) with ADHD (attention-deficit hyperactivity disorder), where other healthy sleeping routines have not worked well enough.

2. What you need to know before you take [Name of the medicinal product]

Do not take [Name of the medicinal product]

- 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 [Name of the medicinal product]:

- if you have other causes of insomnia;
- if you have diabetes or impaired glucose tolerance, as this medicine may increase the level of glucose in your blood (see section 3);
- if you have liver or kidney problems;
- if you have an autoimmune disease (where the body is 'attacked' by its own immune system);
- if you have epilepsy. Melatonin may increase seizure frequency in patients with

- epilepsy;
- if you are elderly;
- if you are a woman of childbearing potential, you must use contraception during treatment with [Name of the medicinal product]. This medicinal product may however be affected by certain contraceptives. Please refer to section ‘Other medicines and [Name of the medicinal product]’ for more information.

Smoking

Smoking may reduce the effects of [Name of the medicinal product]. If you smoke, start to smoke, or quit smoking, your doctor may need to adjust your dose.

Children and adolescents

Do not give this medicine to children or adolescents below 18 years old for the treatment of jet lag. Do not give this medicine to children below 6 years old with ADHD.

Other medicines and [Name of the medicinal product]

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

- Fluvoxamine (used in the treatment of depression and obsessive-compulsive disorder);
- Imipramine (used in the treatment of depression), as both medicines taken together enhance feelings of drowsiness and difficulty in performing tasks;
- Psoralens (used for the treatment of skin diseases such as psoriasis);
- Cimetidine, Omeprazole (used in the treatment of stomach problems such as ulcers);
- Estrogens (used in contraceptives or hormone replacement preparations);
- Ciprofloxacin, norfloxacin and rifampicin (used in the treatment of bacterial infections);
- Carbamazepine and phenytoin (used in the treatment of epilepsy);
- Medicines for pain and inflammation (non-steroidal anti-inflammatory drugs, e.g. acetylsalicylic acid and ibuprofen);
- Benzodiazepines and non-benzodiazepine hypnotics (medicines for insomnia, e.g. midazolam, temazepam, zaleplon, zolpidem, zopiclone), as melatonin may enhance the sedative effect of such medicines, and may enhance certain side effects of zolpidem (morning sleepiness, nausea, confusion);
- Warfarin and other blood-thinning medicines e.g. dabigatran, rivaroxaban, apixaban, edoxaban. It may be necessary to measure the time for the blood to clot, also known as INR- test;
- Nifedipine and other beta-blocker medicines (used in the treatment of high blood pressure);
- Thioridazine (used to treat mental/mood disorders), as both medicines taken together enhance feelings of drowsiness and difficulty in performing tasks;
- Caffeine (stimulant), as melatonin interacts with caffeine.

[Name of the medicinal product] with food and alcohol

Do not eat 2 hours before or 2 hours after taking [Name of the medicinal product]. Do not drink alcohol before, during or after taking [Name of the medicinal product] as it may reduce the effectiveness of melatonin.

Pregnancy, breast-feeding and fertility

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

Contraceptives for fertile women and young girls

Fertile women and young girls should use contraceptives during treatment. [Name of the medicinal product] may be affected by certain contraceptives (see section “Other medicines and [Name of the medicinal product]”), discuss your choice of contraceptives with your doctor.

Pregnancy

[Name of the medicinal product] is not recommended if you or your child are pregnant. Melatonin crosses the placenta, and there is insufficient information on the risk this may pose to the unborn

child.

Breast-feeding

[Name of the medicinal product] is not recommended if you or your child are breast-feeding. Melatonin is excreted in human milk, and a risk to the breast-fed child cannot be excluded.

Driving and using machines

[Name of the medicinal product] can make you feel drowsy. If this happens, you must not drive, cycle, or operate machinery.

3. How to take [Name of the medicinal product]

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

Adults with jet lag

The recommended dose is 0.5 to 5 mg. The maximum daily dose is 5 mg once a day, for maximum 5 days. Take the lowest dose that alleviates symptoms, for the shortest possible time but not longer than 5 days.

Take the dose before bedtime at of destination, when traveling over at least 5 time zones, especially for trips in an easterly direction. The tablets should not be taken before 20:00 or after 04:00.

Children and adolescents aged 6-17 years old with ADHD with insomnia

The recommended starting dose is 0.5 to 2 mg 30-60 minutes before bedtime. If there is no improvement in your child's symptoms, your doctor may increase the dose of [Name of the medicinal product] to determine the most suitable dose for your child. The maximum daily dose is 5 mg regardless the age. The lowest dose possible will be given.

Treatment should be followed up regularly by a doctor to see if it is still appropriate.

Method of administration

Tablet for oral use.

The tablet can be crushed and mixed with water directly before swallowing it.

Food should not be consumed two hours before or two hours after taking [Invented name]

Diabetes

If you have or your child has diabetes or impaired glucose tolerance, food should not be consumed 2 hours before or 2 hours after intake of [Name of the medicinal product].

If you take more [Name of the medicinal product] than you should

If you or your child has accidentally taken too much medicine or if, for example, a child has ingested the medicine by mistake, contact a doctor or hospital.

Taking more than the recommended daily dose may make you feel drowsy.

If you forget to take [Name of the medicinal product]

If you forget to take a dose at bedtime and wake during the night, you may take the forgotten dose but at no later than 04:00.

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

If you stop taking [Name of the medicinal product]

There are no known harmful effects if treatment is interrupted or ended early. The use of [Name of the medicinal product] is not known to cause any withdrawal effects when stopping treatment.

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.

If you experience any of the following serious side effects, you must stop taking [Name of the medicinal product] and contact your doctor immediately:

- Hypersensitivity reaction (allergy like reactions such as itching, difficulty to breathe), facial swelling, swelling of the mouth, swelling of the tongue
- Chest pain

Other possible side effects lister below:

Common side effects (may affect up to 1 in 10 people)

- Headache
- Sleepiness

Uncommon side effects (may affect up to 1 to 100 people)

- Irritability, nervousness, restlessness, anxiety
- Insomnia, abnormal dreams, nightmares
- Migraine, dizziness, nausea
- Lack of energy, restlessness associated with increased activity
- High blood pressure
- Abdominal pain, indigestion, mouth ulceration, dry mouth
- Changes in the composition of your blood that can cause yellowing of the skin and eyes
- Inflammation of the skin, itching, rash, dry skin, night sweats
- Pain in the arms and legs
- Excretion of glucose in the urine, excess protein in the urine
- Menopausal symptoms in women
- Feeling of weakness
- Weight gain
- Liver function test abnormal

Rare side effects (may affect up to 1 to 1000 people)

- Shingles
- Reduced number of white blood cells in the blood
- Reduced number of blood platelets
- Low calcium or sodium levels in the blood
- High level of blood fats
- Changes in mood, aggression, agitation, crying, stress symptoms, disorientation (feeling confused), early morning awakening, increased sex drive, depressed mood, depression
- Fainting, memory impairment, disturbance in attention, dreaming state, restless legs syndrome, poor quality sleep, 'pins and needles' feeling in the skin
- Visual impairment, blurred vision, increased secretion of tears
- Vertigo (a feeling of dizziness or "spinning"), dizziness when standing or sitting
- Chest pain due to angina pectoris, faster heartbeat
- Sudden feeling of heat (hot flush)
- Acid reflux, gastrointestinal disorder, blistering in the mouth, tongue ulceration, stomach upset, vomiting, abnormal bowel sounds, flatulence, increased saliva production, bad breath, abdominal discomfort, inflammation of the stomach lining
- Eczema, erythema, dermatitis of the hands, itchy rash, psoriasis, nail disorders
- Joint inflammation, muscle spasms, neck pain, night cramps
- Increased volume of urine, need to urinate at night, presence of red blood cells in the urine
- Prolonged erection – which might be painful – without sexual stimulation, swelling of the prostate (prostatitis)
- Tiredness, pain, thirst

- Increased liver enzymes, abnormal blood electrolytes and abnormal laboratory tests

Not Known (frequency cannot be estimated from the available data)

- Spontaneous flow of milk from the breasts (also in men)
- High blood sugar levels

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 national reporting system listed in Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Name of the medicinal product]

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 carton and bottle after EXP.

The expiry date refers to the last day of that month.

Store in 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 [Name of the medicinal product] contains

- The active substance is melatonin. One tablet contains 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg, or 5 mg.
- The other excipients microcrystalline cellulose (E 460), pregelatinized starch (E 1404), colloidal anhydrous silica (E 551), magnesium stearate (E 470b).

What [Name of the medicinal product] looks like and contents of the pack

[Name of the medicinal product] 0.5 mg is a white to yellowish, round biconvex tablet with “0” marked on one side, tablet size 7.5 mm.

[Name of the medicinal product] 1 mg is a white to yellowish, round biconvex tablet with “1” marked on one side, tablet size 9.5 mm.

[Name of the medicinal product] 2 mg is a white to yellowish, round biconvex tablet with “2” marked on one side, tablet size 7.0 mm.

[Name of the medicinal product] 3 mg is a white to yellowish, round biconvex tablet with “3” marked on one side, tablet size 8.0 mm.

[Name of the medicinal product] 4 mg is a white to yellowish, round biconvex tablet with “4” marked on one side, tablet size 9.0 mm.

[Name of the medicinal product] 5 mg is a white to yellowish, round biconvex tablet with “5” marked on one side, tablet size 10.0 mm.

[Name of the medicinal product] 0.5 mg and 1 mg tablets is available in a plastic bottle with lid (tamper evident), containing 100 tablets.

[Name of the medicinal product] 2 mg, 3 mg, 4 mg, and 5 mg is available in a plastic bottle with lid (tamper evident), containing 30 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<to be completed nationally>

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