

Package leaflet: Information for the patient

Mellozzan 0.5 mg tablets

Mellozzan 1 mg tablets

Mellozzan 2 mg tablets

Mellozzan 3 mg tablets

Mellozzan 4 mg tablets

Mellozzan 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 Mellozzan is and what it is used for
2. What you need to know before you or your child take Mellozzan
3. How to take Mellozzan
4. Possible side effects
5. How to store Mellozzan
6. Contents of the pack and other information

1. What Mellozzan is and what it is used for

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

Mellozzan is used for 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 or your child take Mellozzan

Do not take Mellozzan

- 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 Mellozzan, if you or your child:

- have diabetes or impaired glucose tolerance, as this medicine may increase the level of glucose in your blood (see section 3);
- have liver or kidney problems;
- have an autoimmune disease (where the body is 'attacked' by its own immune system);
- have epilepsy. Melatonin may increase seizure frequency in patients with epilepsy;
- are a woman of childbearing potential. Contraception should be used during treatment with Mellozzan. This medicinal product may however be affected by certain contraceptives. Please refer to section 'Other medicines and Mellozzan' for more information.

Smoking

Smoking may reduce the effects of Mellozzan. If you or your child smoke, start to smoke, or quit smoking, your doctor may need to adjust the dose.

Children and adolescents

Do not give this medicine to children below 6 years old.

Other medicines and Mellozzan

Tell your doctor or pharmacist if you or your child 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 calcium channel-blocker medicines, beta blockers (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.

Mellozzan with food and alcohol

Do not drink alcohol before, during or after taking Mellozzan as it may reduce the effectiveness of melatonin.

Pregnancy and breast-feeding

If you or your child 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. Mellozzan may be affected by certain contraceptives (see section “Other medicines and Mellozzan”), discuss your choice of contraceptives with your doctor.

Pregnancy

Mellozzan 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

Mellozzan 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

Mellozzan can make you feel drowsy. If this happens, you must not drive, cycle or operate machinery.

3. How to take Mellozzan

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

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 Mellozzan to determine the most suitable dose for your child. The maximum daily dose is 5 mg regardless of 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 before intake and mixed with water.

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 Mellozzan.

If you take more Mellozzan than you should

If you or your child have accidentally taken too much medicine or if, for example, a child has ingested the medicine by mistake, contact a doctor or pharmacist as soon as possible.

Taking more than the recommended daily dose may make you feel drowsy, dizzy, nauseous and/or have a headache.

If you forget to take Mellozzan

If you forget to take a dose at bedtime and wake up 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 Mellozzan

There are no known harmful effects if treatment is interrupted or ended early. The use of Mellozzan 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 or your child experience any of the following serious side effects, you must stop taking Mellozzan and contact your doctor immediately:

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

- Hypersensitivity reaction (allergy like reactions such as itching, difficulty to breathe)
- Angioedema with symptoms such as swelling of the face, tongue, or throat; difficulty swallowing, hives and difficulty breathing.

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

- Chest pain due to angina pectoris.

Other possible side effects listed 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, night sweats
- Migraine, dizziness, nausea
- Tiredness (and lack of energy), restlessness associated with increased activity
- High blood pressure
- Abdominal pain, upper abdominal pain, indigestion
- Mouth ulcers, dry mouth
- Changes in the composition of your blood which can cause yellowing of the skin and eyes
- Skin problems (dermatitis, itching, rash, general itching, dry skin)
- Pain in the arms and legs
- Excretion of glucose in the urine, too much protein in the urine
- Menopausal symptoms
- Feeling of weakness, chest pain
- Liver test abnormalities
- Weight gain.

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

- Shingles (herpes zoster)
- Reduced number of white blood cells in the blood
- Reduced number of platelets in the blood
- Low levels of calcium or sodium in the blood
- High levels of fats in the blood
- Altered mood, aggression, restlessness, crying, stress symptoms, feeling confused (disoriented), early morning awakening, increased sex drive (increased libido), depressed mood, depression
- Fainting, memory impairment, attention disorder, dreamy state, unpleasant feeling in the legs (restless legs syndrome), poor sleep quality, “pins and needles” feeling (paresthesia)
- Impaired visual acuity, blurred vision, watery eyes
- A feeling of dizziness or spinning (vertigo), dizziness when getting up or sitting down
- Feeling your heartbeat
- Hot flushes
- Acid reflux, gastrointestinal disorder, blistering in the mouth, tongue ulceration, gastrointestinal upset, vomiting, abnormal bowel sounds, wind (flatulence), increased salivation, bad breath, abdominal discomfort, gastric disorder, inflammation of the gastric mucosa
- Skin problems (eczema, redness, hand dermatitis, psoriasis, rash generalized, itchy rash), nail disorders
- Joint inflammation (arthritis), muscle cramps, neck pain, night cramps
- Increased amounts of urine, red blood cells in the urine, urination at night
- Prolonged erection – that might be painful – without sexual stimulation, inflammation or swelling of the prostate
- Tiredness, pain, thirst
- Increased liver enzymes, abnormal blood electrolytes and abnormal laboratory tests

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

- High blood sugar level
- Abnormal milk secretion.

Reporting of side effects

If you or your child 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 Mellozzan

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 Mellozzan 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 are microcrystalline cellulose (E 460), pregelatinized starch (E 1404), colloidal anhydrous silica (E 551) and magnesium stearate (E 470b).

What Mellozzan looks like and contents of the pack

Mellozzan 0.5 mg is a white to yellowish, round tablet with “0” marked on one side; tablet size 7.5 mm.

Mellozzan 1 mg is a white to yellowish, round tablet with “1” marked on one side, tablet size 9.5 mm.

Mellozzan 2 mg is a white to yellowish, round tablet with “2” marked on one side, tablet size 7.0 mm.

Mellozzan 3 mg is a white to yellowish, round tablet with “3” marked on one side, tablet size 8.0 mm.

Mellozzan 4 mg is a white to yellowish, round tablet with “4” marked on one side, tablet size 9.0 mm.

Mellozzan 5 mg is a white to yellowish, round tablet with “5” marked on one side, tablet size 10.0 mm.

Mellozzan is available in a plastic bottle with lid (tamper evident), containing 26, 30, 60 or 100 tablets and in blister packs with 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<to be completed nationally>

This leaflet was last revised on 28-NOV-2025