

## Package leaflet: Information for the patient

**Melatonin AGB Pharma 0.5 mg tablets**

**Melatonin AGB Pharma 1 mg tablets**

**Melatonin AGB Pharma 2 mg tablets**

**Melatonin AGB Pharma 3 mg tablets**

**Melatonin AGB Pharma 4 mg tablets**

**Melatonin AGB Pharma 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 <Invented name> is and what it is used for
2. What you need to know before you take <Invented name>
3. How to take <Invented name>
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information

### **1. What <Invented name> is and what it is used for**

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

<Invented name> is used for:

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

### **2. What you need to know before you take <Invented name>**

#### **Do not take <Invented name>**

- 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, pharmacist or nurse before taking <Invented name> if you have:

- diabetes or impaired glucose tolerance, as this medicine may increase the level of glucose in your blood
- liver or kidney problems

- an autoimmune disease (where the body is 'attacked' by its own immune system)
- epilepsy since <Invented name> may increase seizure frequency in patients with epilepsy
- if you smoke. Smoking may reduce the effect of <Invented name>. Your doctor may need to adjust your dose.
- if you are a woman of childbearing potential. Contraceptives should be used during treatment with <invented name>. This medicinal product may however be affected by certain contraceptives, see the section 'Other medicines and <Invented name>' for more information.

It is unclear if significantly older people are sensitive to melatonin.

### **Children and adolescents**

Do not give this medicine to children or adolescents under 18 years of age to treat jet lag as its safety and efficacy are unknown for this indication.

Do not give this medicine to children with ADHD below 6 years to treat insomnia as its safety and efficacy are unknown.

### **Other medicines and <Invented name>**

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

If <Invented name> is taken at the same time as the following medicines, it can affect the way that <Invented name> or the other medicine works:

- Depression (e.g. fluvoxamine, citalopram)
- Sleep disorder (e.g. zolpidem)
- Epilepsy (carbamazepine, phenytoin)
- Ulcers (cimetidine, omeprazole)
- Skin disorders (psoralens)
- Heart conditions (verapamil)
- High blood pressure (e.g. nifedipine, beta-blockers)
- Bacterial infections (ciprofloxacin and norfloxacin)
- Tuberculosis (rifampicin)
- Prevention and treatment of blood clots (e.g. warfarin)
- Contraceptives containing ethinylestradiol and gestagen
- Hormone replacement therapy due to menopause problems
- Pain and inflammation (non-steroidal anti-inflammatory medicines, e.g. acetylsalicylic acid and ibuprofen)
- Caffeine

### **<Invented name> with alcohol**

Do not drink alcohol in connection with taking <Invented name>, as it may reduce the effect 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, you should not use <Invented name>.

### *Contraceptives for fertile women and young girls*

Fertile women and young girls should use contraceptives when taking <Invented name>. Some contraceptives may increase melatonin levels in the body (see "Other medicines and <Invented name>").

### *Pregnancy*

<Invented name> is not recommended if you are pregnant. Melatonin crosses the placenta and there is insufficient information on the risk this may pose to the unborn child.

### *Breast-feeding*

<Invented name> is not recommended if you are breast-feeding. Melatonin passes into human milk, and a risk to the breast-fed child cannot be excluded.

### **Driving and using machines**

<Invented name> can make you feel drowsy. If this happens, you must not drive or operate machinery.

### **<Invented name> contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## **3. How to take <Invented name>**

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

### ***Adults with jet lag***

The standard starting dose is 3 mg daily for a maximum of 5 days. The dose can be gradually adjusted within the range of 0.5 to 5 mg per day to alleviate your symptom. The lowest dose that alleviates your symptom should be used for the shortest time. Maximum treatment time is 5 days.

The first dose should be taken on arrival at destination at your usual bedtime. Intake on the following days should also be at your usual bedtime. The tablets should not be taken before 20:00 hr or after 04:00 hr.

<Invented name> may be taken for a maximum of 16 treatment periods per year.

### ***Insomnia in children and adolescents with ADHD***

Melatonin treatment is prescribed by your doctor because other treatable causes of the sleep disorder have been ruled out and other sleep-promoting measures have been insufficient.

Recommended starting dose is 0.5 to 2 mg, taken 30-60 minutes before bedtime. The dose will be adjusted individually to a maximum of 5 mg per day, regardless of age. The lowest dose possible will be given.

Treatment should be followed up regularly by a doctor (at least every 6 months is recommended) to see if it is still appropriate. Treatment should be interrupted once a year to see if treatment is still needed.

### ***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 <Invented name>, see Warnings and precautions.

### ***How to take the medicine***

<Invented name> should be swallowed. If needed, the tablet can be crushed and dispersed in water before intake.

Food should not be consumed 2 h before or 2 h after intake of <Invented name>.

**If you take more <Invented name> 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, hospital, or pharmacist as soon as possible.

Taking more than the recommended daily dose may give you symptoms such as drowsiness, headache, dizziness, and nausea.

**If you forget to take <Invented name>**

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 hr.

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

**If you stop taking <Invented name>**

There are no known harmful effects if treatment is interrupted or ended. The use of <Invented name> 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, pharmacist or nurse.

#### **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, stop taking <Invented name> and contact a doctor immediately:

- Hypersensitivity reaction with symptoms such as swelling of face, swelling of mouth, swelling of tongue (Frequency not known: frequency cannot be established from the available data)
- Chest pain (Rare side effects: may affect up to 1 in 1000 people)

**Other side effects**

If you experience any of the following side effects, contact a doctor and/or seek medical advice:

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, anxiety
- Insomnia, abnormal dreams, nightmares
- Migraine, dizziness

- Lethargy (tiredness) and lack of energy, restlessness associated with increased activity
- High blood pressure
- Abdominal pain, indigestion, mouth ulceration, dry mouth, nausea
- Changes in the composition of your blood which can cause yellowing of the skin and eyes
- Inflammation of the skin, itching, rash, dry skin, night sweats
- Pain in arms and legs
- Excretion of glucose in the urine, excess proteins in the urine
- Menopausal symptoms
- Feeling of weakness, chest pain
- Abnormal liver function tests
- Weight gain

Rare side effects: may affect up to 1 in 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
- Altered mood, aggression, crying, stress symptoms, disorientation, early morning awakening, increased sex drive, depressed mood, depression
- Fainting, memory impairment, disturbance in attention, dreamy state, restless legs syndrome, poor quality sleep, 'pins and needles' feeling
- Visual impairment, blurred vision, watery eyes
- Vertigo (a feeling of dizziness or "spinning"), dizziness when standing or sitting
- Feeling your heartbeat
- Hot flushes
- Acid reflux, gastrointestinal disorder, blistering in the mouth, tongue ulceration, stomach upset, vomiting, abnormal bowel sounds, wind, excess saliva production, bad breath, abdominal discomfort, stomach disorder, inflammation of the stomach lining
- Eczema, skin rash, hand skin inflammation, itchy rash, psoriasis, nail disorder
- Arthritis, muscle spasms, neck pain, night cramps
- Passing large volumes of urine, urinating during the night, presence of red blood cells in the urine
- Prolonged erection - that might be painful - without sexual stimulation, inflammation of the prostate gland
- Tiredness, pain, thirst

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

Frequency not known: frequency cannot be established from the available data

- Abnormal milk secretion
- Hallucinations (e.g. seeing, feeling or hearing things that don't exist)
- Drowsiness, sedation
- High blood sugar

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 <Invented name>**

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

This medicinal product does not require any special temperature storage conditions. 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 <Invented name> contains**

- The active substance is melatonin 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg or 5 mg.
- The other ingredients are microcrystalline cellulose (E 460), mannitol (E 421), silica colloidal anhydrous (E 551), croscarmellose sodium (E 468) and magnesium stearate (E 470b).

### **What <Invented name> looks like and contents of the pack**

<Invented name> 0.5 mg is a white to almost white, round, biconvex tablet with "0.5" marked on one side. Tablet size is 8 mm.

<Invented name> 1 mg is a white to almost white, round, biconvex tablet with "1" marked on one side. Tablet size is 8 mm.

<Invented name> 2 mg is a white to almost white, round, biconvex tablet with "2" marked on one side. Tablet size is 8 mm.

<Invented name> 3 mg is a white to almost white, round, biconvex tablet with "3" marked on one side. Tablet size is 8 mm.

<Invented name> 4 mg is a white to almost white, round, biconvex tablet with "4" marked on one side. Tablet size is 8 mm.

<Invented name> 5 mg is a white to almost white, round, biconvex tablet with "5" marked on one side. Tablet size is 8 mm.

<Invented name> is available in plastic bottle packs, with either tamper proof caps or child-resistant and tamper proof caps. Pack sizes of 30 or 100 tablets per bottle.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

[To be completed nationally]

**This leaflet was last revised in 2023-10-24**