

## **Package leaflet: Information for the user**

**Melatan 1 mg tablets**

**Melatan 2 mg tablets**

**Melatan 4 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 <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**

<Invented name> contains the active substance melatonin, which belongs to a natural group of hormones produced by the body.

Melatonin helps to 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 traveling across several time zones.
- Insomnia in children and adolescents (6 to 17 years old) with ADHD, where other healthy sleeping routines has 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 or pharmacist before taking <Invented name>, if you suffer from

- epilepsy
- kidney disease
- liver disease
- diabetes or impaired glucose tolerance, as this medicine may increase the level of glucose in your blood
- autoimmune disease (where the body is 'attacked' by its own immune system).

If you suffer from liver disease, kidney disease or autoimmune disease, the use of <Invented name> is not recommended.

Women of childbearing potential should use contraception during the treatment. <Invented name> may however be affected by certain contraceptives, see the section ‘Other medicines and <Invented name>’ and ask your doctor for more information.

### **Children and adolescents**

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

Do not give this medicine to children below 6 years 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.

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)
- 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
- Benzodiazepines and non-benzodiazepine hypnotics (medicines used to induce sleep such as zaleplon, zolpidem and zopiclone).
- Thioridazine (for the treatment of schizophrenia)
- Imipramine (for the treatment of depression)
- Warfarin (used to prevent blood clotting) – INR (blood clotting test) may be necessary to verify more specifically.
- Beta-blockers (used to treat high blood pressure), as these medicines may reduce the effects of melatonin.
- Nifedipine (used to treat high blood pressure), as melatonin may reduce the effect of nifedipine
- NSAID medicines such as acetylsalicylic acid and ibuprofen.
- Smoking may decrease the effect of melatonin

### **<Invented name> with food, drink and alcohol**

Do not drink alcohol before, during or after taking <Invented name>, because it reduces the effectiveness of <Invented name>.

### **Pregnancy and breast-feeding**

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

#### Contraceptives for fertile women and young girls

Fertile women and young girls should use contraceptives when taking <Invented name>. Because some contraceptives may increase melatonin levels in the body, the choice of contraceptive should be discussed with a doctor (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 is excreted in human milk, and a risk to the sucking child cannot be excluded.

### **Driving and using machines**

[product name] may cause drowsiness and may decrease alertness for several hours after intake. Therefore, this medicine should not be taken prior to driving or using machines.

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

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

#### Jet lag in adults

The recommended dose is 1-5 mg daily for a maximum of 5 days.

Maximum daily dose is 5 mg for 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 tablet should not be taken before 20:00 hours or after 04:00 hours at destination.

#### Insomnia in children and adolescents aged 6-17 years with ADHD

The recommended starting dose is 1-2 mg 30-60 minutes before bedtime.

The dose will be adjusted individually to a maximum of 5 mg daily, 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.

#### Method of administration

Tablets should be swallowed with a glass of water.

Food should not be consumed 2 hours before or 2 hours after intake of <invented name>.

#### **If you take more <Invented name> than you should**

If you have taken too much of your medicine or if a child has accidentally taken the medicine, contact always doctor or nearest 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 <Invented name>**

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

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

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

There are not known harmful effects if treatment is interrupted or ended early. 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 or pharmacist.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Potential adverse reactions are headache, nausea, loss of appetite, dizziness, daytime sleepiness, and disorientation in both adults and children. For other side effects that may occur, see below information.

When used for various sleep disorders melatonin has been reported to cause spectrum of adverse effects.

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

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

- Loss of consciousness or fainting
- Severe chest pain due to angina

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

- Hypersensitivity reaction
- Swelling of mouth or tongue

If you experience any of the following other 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
- chest 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
- depression
- altered mood
- aggression, agitation
- crying
- stress symptoms
- early morning awakening
- increased sex drive
- depressed mood
- disorientation

- memory impairment
- disturbance in attention
- dreamy state
- restless legs syndrome
- poor quality sleep
- ‘pins and needles’ feeling
- feeling your heartbeat
- visual impairment
- watery eyes
- vertigo (a feeling of dizziness or “spinning”)
- 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
- psoriasis
- eczema
- skin rash
- hand dermatitis
- itchy rash
- nail disorder
- arthritis
- muscle spasms
- neck pain
- night cramps
- presence of blood in the urine
- passing large volumes of urine
- urinating during the night
- prolonged erection that might be painful
- inflammation of the prostate gland
- tiredness
- pain
- thirst
- reduced number of white blood cells in the blood
- reduced blood platelets, which increases risk of bleeding or bruising
- increased liver enzymes
- abnormal blood electrolytes
- abnormal laboratory tests

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

- swelling of the skin
- 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 [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 (EXP). The expiry date refers to the last day of that month.

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.

1 mg tablets in blister packs:

Store below 25°C.

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

1 mg tablets in tablet container and 2 mg and 4 mg tablets in blister packs and in tablet container:

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

## **6. Contents of the pack and other information**

### **What <Invented name> contains**

The active substance is melatonin.

Each tablet contains 1 mg, 2 mg, or 4 mg of melatonin.

The other ingredients are:

Calcium hydrogen phosphate dihydrate, microcrystalline cellulose, magnesium stearate, silica colloidal anhydrous, starch pregelatinised.

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

1 mg tablets: white to beige, capsule-shaped tablet. Dimensions of the tablet are 5 mm x 10 mm.

2 mg tablets: white to beige, round, convex tablet. Diameter of the tablet is 6 mm.

4 mg tablets: white to beige, round, convex tablet. Diameter of the tablet is 7 mm.

10, 30, 50 and 100 tablets in blister packs (PVC/Aluminium).

10, 30, 50 and 100 tablets in a plastic bottle with a plastic cap.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

[To be completed nationally]

### **Manufacturer**

[To be completed nationally]

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

Melatal: Denmark, Norway

Melatan: Sweden

Sental: Poland

Melatonin Vitabalans: Czech Republic, Estonia, Finland, Germany, Hungary, Latvia, Slovakia, Slovenia

[To be completed nationally]: Lithuania

**This leaflet was last revised in 2026-02-24**