

# MELATONIN ARX

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using MELATONIN ARX?

MELATONIN ARX contains the active ingredient Melatonin. MELATONIN ARX is used to improve sleep quality and morning alertness in patients over 55 years of age with poor quality of sleep.

For more information, see Section [1. Why am I using MELATONIN ARX?](#) in the full CMI.

### 2. What should I know before I use MELATONIN ARX?

Do not use if you have ever had an allergic reaction to MELATONIN ARX or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use MELATONIN ARX?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with MELATONIN ARX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use MELATONIN ARX?

- Adults 55 years and over: Take one tablet after food, 1-2 hours before you go to bed.

More instructions can be found in Section [4. How do I use MELATONIN ARX?](#) in the full CMI.

### 5. What should I know while using MELATONIN ARX?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using MELATONIN ARX.</li><li>If you become pregnant while taking MELATONIN ARX, stop taking the tablets and tell your doctor immediately.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not give MELATONIN ARX to anyone else, even if they have the same condition as you.</li><li>Do not take more than the recommended dose unless your doctor tells you to.</li><li>Do not use this medicine to treat any other complaints unless your doctor tells you to.</li><li>Do not drink alcohol before or after taking this medicine</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Driving or operating machinery is not recommended.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>Do not drink alcohol before or after taking this medicine</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep your tablets in the blister pack until it is time to take them.</li><li>Keep MELATONIN ARX away from sunlight.</li><li>Keep the medicine in a cool dry place where the temperature stays below 25°C.</li></ul>

For more information, see Section [5. What should I know while using MELATONIN ARX?](#) in the full CMI.

### 6. Are there any side effects?

MELATONIN ARX has been shown to improve the sleep of most people aged over 55 years, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects. Ask your doctor or pharmacist to answer any questions you may have.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# MELATONIN ARX

Active ingredient(s): *Melatonin*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using MELATONIN ARX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MELATONIN ARX.**

Where to find information in this leaflet:

- [1. Why am I using MELATONIN ARX?](#)
- [2. What should I know before I use MELATONIN ARX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MELATONIN ARX?](#)
- [5. What should I know while using MELATONIN ARX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using MELATONIN ARX?

MELATONIN ARX contains the active ingredient **melatonin**. Melatonin is a naturally occurring hormone produced in the body.

It works by controlling the circadian rhythms and increasing the propensity to sleep.

MELATONIN ARX is used for the short term treatment of primary insomnia characterized by poor quality of sleep in patients who are aged 55 years of age or over

### 2. What should I know before I use MELATONIN ARX?

#### Warnings

Do not use MELATONIN ARX if:

- you are allergic to melatonin, or any of the ingredients listed at the end of this leaflet.  
Always check the ingredients to make sure you can use this medicine.
- Do not use in adults or children under 55 years of age.
- Alcohol should not be taken with melatonin. Do not take melatonin if you have been drinking alcohol, intend to drink alcohol or believe that you may have alcohol in your blood stream.

Check with your doctor or pharmacist if you:

- have any other medical conditions:
  - Liver problems
  - Kidney problems
  - An autoimmune disease

- A hereditary problem of galactose intolerance, LAP lactase deficiency or glucose-galactose malabsorption
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

- Do not take melatonin if you are pregnant or breastfeeding.

This medicine has not been studied in pregnant or breastfeeding women.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and melatonin may interfere with each other. These include:

- hypnotics or tranquilisers (e.g. benzodiazepines)
- certain medicine used to treat mood disorders (e.g. fluvoxamine, thioridazine and imipramine)
- contraceptives or hormone replacement therapy containing oestrogen
- quinolones and rifampicin, used to treat infections
- carbamazepine, used to treat epilepsy
- cimetidine
- psoralens used to treat skin problems (e.g. psoriasis)
- alcohol
- caffeine

#### Some medicines may interfere with MELATONIN ARX and affect how it works.

The effect of adding melatonin to other medicines used to treat insomnia has not been examined. It is not known if melatonin will increase or decrease the effects of other treatments for insomnia.

These medicines may be affected by melatonin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

**Medicines that may increase the effect of MELATONIN ARX include:**

- Quinolones

- Fluvoxamine
- 5- or 8—methoxypsoralen
- Cimetidine
- Oestrogens

Medicines that may **reduce** the effect of MELATONIN ARX include:

- Carbamazepine and rifampicin

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MELATONIN ARX.**

#### 4. How do I use MELATONIN ARX?

##### How much to take / use

- The usual dose of melatonin is one tablet once a day. There is no evidence that taking more than the recommended dose will increase the effect of melatonin.
- Swallow the tablet whole with a glass of water. Do not crush, chew or divide your tablet. Each melatonin tablet has been specially designed to release the right dose of medicine while you sleep. If you crush, chew or divide the tablet they will not work properly
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.

##### When to take / use MELATONIN ARX

- MELATONIN ARX should be used at about the same time each day, about 1-2 hours before you go to bed.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- Melatonin should be taken with food

##### Principles of good sleep hygiene:

- Go to bed and arise at the same time daily
- Engage in relaxing activities before bedtime
- Exercise regularly but not in the late evening
- Avoid eating meals or large snacks just before bedtime
- Eliminate daytime naps
- Avoid caffeine-containing drinks after midday
- Avoid alcohol or the use of nicotine late in the evening
- Minimise external disruption (e.g. light and noise)
- If you are unable to sleep, do not become anxious; leave the bedroom and participate in relaxing activities such as reading or listening to music until you are tired.

##### If you use too much MELATONIN ARX

If you think that you have used too much MELATONIN ARX, you may need urgent medical attention.

##### You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

#### 5. What should I know while using MELATONIN ARX?

##### Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking melatonin.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.
- If you become pregnant while taking melatonin, stop taking the tablets and tell your doctor immediately.

Remind any doctor, dentist or pharmacist you visit that you are using MELATONIN ARX.

##### Things you should not do

- Do not take this medicine to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you
- Do not take more than the recommended dose unless your doctor tells you to.
- Do not drink alcohol before or after taking this medicine.

##### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how MELATONIN ARX affects you.**

Melatonin rarely causes drowsiness. Nevertheless, it is not recommended to drive or operate machinery for 8 hours after you take it. Melatonin does not impair morning alertness, but if you suffer from drowsiness during the day you should consult your doctor.

##### Drinking alcohol

**Tell your doctor or pharmacist if you drink alcohol.**

Alcohol reduces the effectiveness of melatonin on sleep. The prolonged release characteristics of melatonin may result in immediate release of melatonin.

##### Looking after your medicine

- Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack, they may not keep well.
- Keep your medicine in a cool dry place where the temperature stays below 25°C. Keep it away from sunlight.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

### Uncommon side effects

Less serious side effects	What to do
<p><b>Psychiatric Disorder</b></p> <ul style="list-style-type: none"> <li>• Irritability, nervousness, restlessness, insomnia, abnormal dreams or anxiety, nightmares.</li> </ul> <p><b>Nervous System Disorders</b></p> <ul style="list-style-type: none"> <li>• Migraine, lethargy, psychomotor hyperactivity (restlessness associated with increased activity), dizziness, somnolence (tiredness), headache</li> </ul> <p><b>Vascular Disorders</b></p> <ul style="list-style-type: none"> <li>• High blood pressure</li> </ul> <p><b>Gastrointestinal Disorder</b></p> <ul style="list-style-type: none"> <li>• Abdominal pain (upper), indigestion, mouth ulceration, dry mouth, nausea</li> </ul> <p><b>Hepatobiliary Disorders</b></p> <ul style="list-style-type: none"> <li>• Hyperbilirubinaemia (changes in the composition of your blood which could cause yellowing of the skin or eyes (jaundice))</li> </ul> <p><b>Skin and Subcutaneous Tissue Disorders</b></p> <ul style="list-style-type: none"> <li>• Inflammation of the skin (dermatitis), night sweats, pruritis (itching), rash, dry skin</li> </ul> <p><b>Musculoskeletal and Connective Tissue Disorders</b></p> <ul style="list-style-type: none"> <li>• Pain in extremities</li> </ul> <p><b>Reproductive System and Breast Disorders</b></p> <ul style="list-style-type: none"> <li>• Menopausal symptoms</li> </ul>	<p><b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b></p>

<p><b>General Disorders and Administration Site Conditions</b></p> <ul style="list-style-type: none"> <li>• Asthenia (feeling of weakness), chest pain</li> </ul> <p><b>Renal and Urinary Disorders</b></p> <ul style="list-style-type: none"> <li>• Excretion of glucose in urine, excess proteins in the urine</li> </ul> <p><b>Investigations</b></p> <ul style="list-style-type: none"> <li>• Liver Function Test Abnormal, weight increase</li> </ul>	
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### Rare side effects

Serious side effects	What to do
<p><b>Infections and Infestations</b></p> <ul style="list-style-type: none"> <li>• Shingles</li> </ul> <p><b>Blood and Lymphatic System Disorders</b></p> <ul style="list-style-type: none"> <li>• Reduced number of white blood cells in the blood, decreased number of platelets in the blood</li> </ul> <p><b>Cardiac Disorders</b></p> <ul style="list-style-type: none"> <li>• Severe chest pain due to angina, feeling your heartbeat (palpitations).</li> </ul> <p><b>Immune System Disorders</b></p> <ul style="list-style-type: none"> <li>• Hypersensitivity reaction</li> </ul> <p><b>Metabolism and Nutrition Disorders</b></p> <ul style="list-style-type: none"> <li>• High level of fatty molecules in the blood, low serum calcium levels in the blood, low sodium levels in the blood</li> </ul> <p><b>Psychiatric Disorders</b></p> <ul style="list-style-type: none"> <li>• Altered mood, aggression, agitation, crying, stress symptoms, disorientation, early morning awakening, increased sex drive, depressed mood, depression</li> </ul> <p><b>Nervous System Disorders</b></p> <ul style="list-style-type: none"> <li>• Loss of consciousness or fainting, memory impairment, disturbance in attention, dreamy state, restless legs syndrome, poor quality sleep, 'pins and needles' feeling (paresthesia)</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> <p><b>The list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.</b></p>

**Eye Disorders**

- Reduced visual acuity (visual impairment), blurred vision, watery eyes

**Ear and Labyrinth Disorders**

- Dizziness when standing or sitting, vertigo

**Vascular Disorders**

- Hot flushes

**Gastrointestinal Disorders**

- Gastro-oesophageal reflux, gastrointestinal disorder, blistering in the mouth, tongue ulceration, gastrointestinal upset, vomiting, abnormal bowel sounds, flatulence (wind), salivary hypersecretion (excess saliva production), halitosis (bad breath), abdominal discomfort, gastric disorder, inflammation of the stomach lining

**Skin and Subcutaneous Tissue Disorders**

- Eczema, erythema (skin rash), hand dermatitis, psoriasis, pruritic rash (itchy rash), nail disorder

**Musculoskeletal and Connective Tissue Disorders**

- Arthritis, muscle spasms, neck pain, night cramps

**Reproductive System and Breast Disorders**

- Increased duration of erection, inflammation of the prostate gland

**General Disorders and Administration Site Conditions**

- Tiredness, pain, thirst

**Renal and Urinary Disorders**

- Passing large volumes of urine, presence of red blood cells in the urine, urination during the night

**Investigations**

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

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

**Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**7. Product details**

This medicine is available with a doctor's prescription.

**What MELATONIN ARX contains**

<b>Active ingredient (main ingredient)</b>	Melatonin 2mg
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• Ammonio methacrylate copolymer type B</li> <li>• Calcium hydrogen phosphate dihydrate</li> <li>• Lactose monohydrate</li> <li>• Colloidal anhydrous silica</li> <li>• Purified talc</li> <li>• Magnesium stearate</li> </ul>
<b>Potential allergens</b>	Contains Lactose

**Do not take this medicine if you are allergic to any of these ingredients.**

**What MELATONIN ARX looks like**

MELATONIN ARX is a white to off-white round bi-convex shaped tablet. (Aust R 250294).

**Who distributes MELATONIN ARX**

Apotex Pty Ltd  
16 Giffnock Avenue,  
Macquarie Park, 2113 New South Wales  
Australia

This leaflet was prepared in July 2021.