

## 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 SomniCare?

SomniCare contains the active ingredient Melatonin. SomniCare 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 SomniCare?](#) in the full CMI.

### 2. What should I know before I use SomniCare?

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

**Talk to your doctor or pharmacist 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 SomniCare?](#) in the full CMI.

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

Some medicines may interfere with SomniCare 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 SomniCare?

- 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 SomniCare?](#) in the full CMI.

### 5. What should I know while using SomniCare?

<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 SomniCare.</li><li>If you become pregnant while taking SomniCare, stop taking the tablets and tell your doctor or pharmacist immediately.</li><li>Go to bed and arise at the same time daily</li><li>Engage in relaxing activities before bedtime</li><li>Exercise regularly but not in the late evening</li><li>Avoid eating meals or large snacks just before bedtime</li><li>Eliminate daytime naps</li><li>Avoid caffeine-containing drinks after midday</li><li>Avoid alcohol or the use of nicotine late in the evening</li><li>Minimise external disruption (e.g. light and noise)</li><li>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.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not give SomniCare 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 or pharmacist tells you to.</li><li>Do not use this medicine to treat any other complaints unless your doctor or pharmacist 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>SomniCare rarely causes drowsiness, nevertheless it is not recommended to drive or operate machinery for 8 hours after you take it.</li><li>SomniCare does not impair morning alertness, but if you suffer from drowsiness during the day you should consult your doctor or pharmacist.</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 SomniCare 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 SomniCare?](#) in the full CMI.

## 6. Are there any side effects?

The active ingredient melatonin 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.

# SomniCare

Active ingredient: *Melatonin*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using SomniCare. **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 SomniCare.**

Where to find information in this leaflet:

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

### 1. Why am I using SomniCare?

SomniCare contains the active ingredient **Melatonin**. The active substance of SomniCare, melatonin, belongs to a group of naturally occurring hormones produced in the body.

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

**SomniCare is used to improve sleep quality and morning alertness in patients over 55 years of age with poor quality of sleep.**

### 2. What should I know before I use SomniCare?

#### Warnings

**Do not use SomniCare 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.
- you have been drinking alcohol or intend to drink alcohol or believe that you may have alcohol in your blood stream.
- you are pregnant or breast-feeding. SomniCare has not been studied in pregnant or breast-feeding women.

**Check with your doctor or pharmacist if you:**

- have or have had the following medical conditions:
  - suffer from liver problems
  - suffer from kidney problems

- If you suffer from an autoimmune disease
- have a rare hereditary problem of galactose intolerance, the LAPP lactase deficiency or glucose-galactose malabsorption

- take any medicines for any other condition
- Do not give SomniCare to a child or adolescent. There is no experience with its use in children or adolescents under 18 years old.

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

Do not take SomniCare if you are pregnant or breast-feeding. SomniCare has not been studied in pregnant or breast-feeding 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 may interfere with SomniCare and affect how it works.**

These include:

- hypnotics and tranquilisers (e.g. benzodiazepine),
- fluvoxamine, thioridazine and imipramine (used to treat depression or psychiatric problems),
- oestrogen (contraceptives or hormone replacement therapy),
- cimetidine and psoralens (used to treat skin problems e.g. psoriasis)
- alcohol
- caffeine

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

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

### 4. How do I use SomniCare?

#### How much to take / use

- The standard dose of SomniCare is one tablet once a day. There is no evidence that taking more than the recommended dose will increase the effect of SomniCare.

- Swallow your tablet whole with a full glass of water.
- **Do not crush, chew or divide your tablet.**
- Each SomniCare 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 SomniCare**

- SomniCare should be used after food, 1-2 hours before you go to bed.

### **If you forget to use SomniCare**

SomniCare should be used regularly at the same time each day. If you miss your dose at the usual time, take another as soon as you remember, before going to bed or wait until it is time for your next dose.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

### **If you use too much SomniCare**

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

**You should immediately:**

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

### **Things you should do**

- 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.

### **Call your doctor or pharmacist straight away if you:**

- If you become pregnant while taking SomniCare, stop taking the tablets and tell your doctor or pharmacist immediately.
- Remind any doctor, dentist or pharmacist you visit that you are using SomniCare.

### **Things you should not do**

- Do not give SomniCare to anyone else, even if they have the same condition as you.
- Do not take more than the recommended dose unless your doctor or pharmacist tells you to.
- Do not use this medicine to treat any other complaints unless your doctor or pharmacist 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 SomniCare affects you.**

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

### **Drinking alcohol**

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

Do not drink alcohol before or after taking this medicine.

### **Looking after your medicine**

- Keep SomniCare away from sunlight.
- Store below 25 °C.

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 about side effects.

## Uncommon side effects

Less serious side effects	What to do
<b>Psychiatric Disorders</b> <ul style="list-style-type: none"> <li>Irritability, nervousness, restlessness insomnia, abnormal dreams, anxiety, nightmares</li> </ul> <b>Nervous System Disorders</b> <ul style="list-style-type: none"> <li>Migraine, lethargy, psychomotor hyperactivity (restlessness associated with increased activity), dizziness, somnolence (tiredness), headache</li> </ul> <b>Vascular Disorders</b> <ul style="list-style-type: none"> <li>High blood pressure</li> </ul> <b>Gastrointestinal Disorders</b> <ul style="list-style-type: none"> <li>Abdominal pain (upper), indigestion, mouth ulceration, dry mouth, nausea</li> </ul> <b>Hepatobiliary Disorders</b> <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> <b>Skin and Subcutaneous Tissue Disorders</b> <ul style="list-style-type: none"> <li>Inflammation of the skin (dermatitis), night sweats, pruritis (itching), rash, dry skin</li> </ul> <b>Musculoskeletal and Connective Tissue Disorders</b> <ul style="list-style-type: none"> <li>Pain in extremities</li> </ul> <b>Reproductive System and Breast Disorders</b> <ul style="list-style-type: none"> <li>Menopausal symptoms</li> </ul> <b>General Disorders and Administration Site Conditions</b> <ul style="list-style-type: none"> <li>Asthenia (feeling of weakness), chest pain</li> </ul> <b>Renal and Urinary Disorders</b> <ul style="list-style-type: none"> <li>Excretion of glucose in urine, excess proteins in the urine</li> </ul> <b>Investigations</b> <ul style="list-style-type: none"> <li>Liver Function Test Abnormal, weight increase</li> </ul>	<b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b>

## Rare side effects

Serious side effects	What to do
<b>Infections and Infestations</b> <ul style="list-style-type: none"> <li>Shingles</li> </ul> <b>Blood and Lymphatic System Disorders</b> <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> <b>Cardiac Disorders</b> <ul style="list-style-type: none"> <li>Severe chest pain due to angina, feeling your heartbeat (palpitations).</li> </ul> <b>Immune System Disorders</b> <ul style="list-style-type: none"> <li>Hypersensitivity reaction</li> </ul> <b>Metabolism and Nutrition Disorders</b> <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> <b>Psychiatric Disorders</b> <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> <b>Nervous System Disorders</b> <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> <b>Eye Disorders</b> <ul style="list-style-type: none"> <li>Reduced visual acuity (visual impairment), blurred vision, watery eyes</li> </ul> <b>Ear and Labyrinth Disorders</b> <ul style="list-style-type: none"> <li>Dizziness when standing or sitting, vertigo</li> </ul> <b>Vascular Disorders</b> <ul style="list-style-type: none"> <li>Hot flushes</li> </ul>	<b>Call your doctor or pharmacist straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

Serious side effects	What to do
<p><b>Gastrointestinal Disorders</b></p> <ul style="list-style-type: none"> <li>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</li> </ul> <p><b>Skin and Subcutaneous Tissue Disorders</b></p> <ul style="list-style-type: none"> <li>Eczema, erythema (skin rash), hand dermatitis, psoriasis, pruritic rash (itchy rash), nail disorder</li> </ul> <p><b>Musculoskeletal and Connective Tissue Disorders</b></p> <ul style="list-style-type: none"> <li>Arthritis, muscle spasms, neck pain, night cramps</li> </ul> <p><b>Reproductive System and Breast Disorders</b></p> <ul style="list-style-type: none"> <li>Increased duration of erection, inflammation of the prostate gland</li> </ul> <p><b>General Disorders and Administration Site Conditions</b></p> <ul style="list-style-type: none"> <li>Tiredness, pain, thirst</li> </ul> <p><b>Renal and Urinary Disorders</b></p> <ul style="list-style-type: none"> <li>Passing large volumes of urine, presence of red blood cells in the urine, urination during the night</li> </ul> <p><b>Investigations</b></p> <ul style="list-style-type: none"> <li>Increased liver enzymes, abnormal blood electrolytes and abnormal laboratory tests.</li> </ul>	

**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.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is available over-the-counter without a doctor's prescription.

### What SomniCare contains

<b>Active ingredient (main ingredient)</b>	Each SomniCare 2 mg tablet contains 2 mg melatonin as the active ingredient
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>ammonio methacrylate copolymer,</li> <li>calcium hydrogen phosphate dihydrate,</li> <li>lactose monohydrate,</li> <li>anhydrous colloidal silica,</li> <li>talc,</li> <li>magnesium stearate.</li> </ul>

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

### What SomniCare looks like

SomniCare tablets are white to off-white round bi-convex shaped tablets (AUST R 422124).

### Who distributes SomniCare

AFT Pharmaceuticals Pty Ltd.  
113 Wicks Road  
North Ryde, NSW 2113, Australia  
Email: [customer.service@aftpharm.com](mailto:customer.service@aftpharm.com)

This leaflet was prepared in September 2023.