

# VIGISOM<sup>®</sup> Prolonged Release Tablet

Melatonin

## Consumer Medicine Information (CMI)

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### What is in this leaflet

This leaflet contains answers to some common questions about VIGISOM.

**It is particularly important that you read the sections "When to take it" and "How to take it" before you take this medicine.** The leaflet does not contain all the information that is known about VIGISOM.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking VIGISOM against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

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### What VIGISOM is used for

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

The active substance of VIGISOM, melatonin (not of plant or animal origin), 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.

Your doctor, however, may prescribe VIGISOM for another purpose.

**Ask your doctor or pharmacist if you have any questions about why it has been prescribed for you.**

This medicine is only available with a doctor's prescription.

VIGISOM is not addictive.

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### Before you take VIGISOM

#### **When you must not take it**

Do not take VIGISOM if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, or rash, itching or hives on the skin.

Do not take VIGISOM if you have been drinking alcohol or intend to drink alcohol or believe that you may have alcohol, in your blood stream.

Do not take VIGISOM if you are pregnant or breast-feeding. VIGISOM has not been studied in pregnant or breast-feeding women.

**Do not take it after the expiry date printed on the pack.**

If you take it after the expiry date has passed, it may not work as well. The expiry date refers to the last day of the month.

**Do not take it if the packaging is torn or shows signs of tampering.**

If you are not sure whether you should start taking VIGISOM talk to your doctor.

**Before you start to take it**

Tell your doctor if:

1. you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
2. you are pregnant or plan to become pregnant
3. you are breast-feeding or planning to breast-feed
4. 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

Do not give VIGISOM to a child or adolescent. There is no experience with its use in children or adolescents under 18 years old.

**If you have not told your doctor about any of the above, so before you use VIGISOM.**

#### **Taking other medicines**

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may affect the way other medicines work.

Some medicines and VIGISOM may interfere with each other. 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 VIGISOM to other medicines used to treat insomnia has not been examined. It is not known if VIGISOM will increase or decrease the effects of other treatments for insomnia.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking VIGISOM.

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## How to take VIGISOM

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### ***How much to take***

**Take VIGISOM only when prescribed by your doctor.**

The standard dose of VIGISOM is one tablet once a day.

There is no evidence that taking more than the recommended dose will increase the effect of VIGISOM.

### ***How to take it***

Swallow your tablet whole with a full glass of water.

**Do not crush, chew or divide your tablet.**

Each VIGISOM 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 all directions given to you by your doctor carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

### ***When to take it***

After food, 1-2 hours before you go to bed.

### ***How long to take it***

It is important that you continue taking VIGISOM for as long as your doctor prescribes. VIGISOM may be continued for up to thirteen weeks.

### ***If you forget to take it***

If you forget to take your tablet, take another as soon as you remember, before going to bed or wait until it is time for your next dose.

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

**If you are not sure what to do, talk to your doctor or pharmacist.**

If you have trouble remembering to take your VIGISOM, ask your pharmacist for some hints.

### ***If you take too much (overdose)***

**Immediately telephone your doctor or Poisons Information Centre (In Australia 13 11 26 and in New Zealand 0800 POISON [0800 764 766]), or go to your nearest accident and emergency centre, if you think that you or anyone else may have taken too much VIGISOM. Do this even if there are no signs of discomfort or poisoning.**

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## While you are using VIGISOM

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### ***Things you must do***

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking VIGISOM.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking VIGISOM, stop taking the tablets and tell your doctor immediately.

### ***Things you must not do***

**Do not give VIGISOM 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 use this medicine to treat any other complaints unless your doctor tells you to.**

**Do not drink alcohol before or after taking this medicine**

### ***Things to be careful of***

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

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## Side Effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking VIGISOM.**

VIGISOM 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.

**Tell your doctor if you notice any of the following and they worry you.**

These are considered to be uncommon side effects (i.e., likely to occur in fewer than 1 in 100 patients):

Irritability, nervousness, restlessness insomnia, abnormal dreams, anxiety, nightmares, migraine, lethargy, psychomotor hyperactivity (restlessness associated with increased activity), dizziness, somnolence (tiredness), headache, high blood pressure, (upper) abdominal pain, indigestion, mouth ulceration, dry mouth, nausea, hyperbilirubinaemia (changes in the composition of your blood which could cause yellowing of the skin or eyes (jaundice), inflammation of the skin (dermatitis), night sweats, pruritis (itching), rash, dry skin, pain in extremities, menopausal symptoms, asthenia (feeling of weakness), chest pain, excretion of glucose in urine, excess proteins in the urine, abnormal liver function and weight increase.

The following events are considered to be rare (i.e., likely to occur in fewer than 1 in 1,000 patients):

Shingles, reduced number of white blood cells in the blood, decreased number of platelets in the blood, high level of fatty molecules in the blood, severe chest pain due to angina, feeling your heartbeat (palpitations). low serum calcium levels in the blood, low sodium levels in the blood, altered mood, aggression, agitation, crying, stress symptoms, disorientation, early morning awakening, increased sex drive, depressed mood, depression, loss of consciousness or fainting, memory impairment, disturbance in attention, dreamy state, restless legs syndrome, poor quality sleep, 'pins and needles' feeling (paresthesia) reduced visual acuity (visual impairment),

blurred vision, watery eyes, dizziness when standing or sitting, vertigo, hot flushes, 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, eczema, erythema (skin rash), hand dermatitis, psoriasis, pruritic rash (itchy rash), nail disorder, arthritis, muscle spasms, neck pain, night cramps, increased duration of erection, inflammation of the prostate gland, tiredness, pain, thirst, passing large volumes of urine, presence of red blood cells in the urine, urination during the night, increased liver enzymes, abnormal blood electrolytes and abnormal laboratory tests.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them

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## After using VIGISOM

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### Storage

**Keep your tablets in the blister pack until it is time to take them.**

If you take the tablets out of the blister pack they may not keep well.

**Keep VIGISOM away from sunlight.**

**Keep the medicine in a cool dry place where the temperature stays below 25°C.**

**Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.**

**Do not leave it in the car.**

Heat and damp can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

If your doctor tells you to stop taking the tablets or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

## Product description

### What VIGISOM looks like

VIGISOM 2 mg tablets are white to off-white round bi-convex shaped tablets

VIGISOM tablets are available in a 30 tablet pack and a 7 tablet sample pack.

### Ingredients

#### Active ingredient

Each VIGISOM 2 mg tablet contains 2 mg melatonin as the active ingredient

#### Inactive ingredients:

- ammonio methacrylate copolymer type B,
- calcium hydrogen phosphate,
- lactose,
- colloidal anhydrous silica,
- purified talc
- magnesium stearate.

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