PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

VIGISOM prolonged-release tablet

Melatonin

Contains sugar: 80 mg lactose monohydrate per tablet**.**

Read all of this leaflet carefully before you start taking VIGISOM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- VIGISOM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What VIGISOM is and what it is used for
2. What you need to know before you take VIGISOM
3. How to take VIGISOM
4. Possible side effects
5. How to store VIGISOM
6. Contents of the pack and other information

1. What VIGISOM is and what it is used for

The active ingredient of VIGISOM is melatonin, which belongs to a natural group of hormones produced by the body.

VIGISOM is used for the short-term treatment of sleeplessness characterised by poor quality of in patients aged 55 years and older for up to 13 weeks.

2. What you need to know before you take VIGISOM

Do not take VIGISOM

- if you are hypersensitive (allergic) to melatonin, or any of the other ingredients of VIGISOM (listed in section 6).
- if you are pregnant or planning to become pregnant:
- if you are breastfeeding

Warnings and precautions

Special care should be taken with VIGISOM:

- VIGISOM can make you feel drowsy, you should be careful if the drowsiness affects you as it may impair your ability on tasks such as driving, or operating machinery.
- if you have been told you suffer from an auto-immune disease (where the body is “attacked” by its own immune system).
- if you have been told by your doctor that you have an intolerance to some sugars.
- if you smoke. Cigarette smoking may make VIGISOM less effective, because the components of tobacco smoke can increase the breakdown of melatonin by the liver.

Children and adolescents

Do not give VIGISOM to children between the ages of 0 to 18 years.

Other medicines and VIGISOM

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. VIGISOM can interfere with some other medicines such as:

- Fluvoxamine (used for the treatment of depression),
- Psoralens (used to treat skin diseases),
- Cimetidine (used to treat excess stomach acid and stomach ulcers)
- Oestrogens (used in contraceptive or hormone replacement therapy),
- Quinolones and rifampicin (used in the treatment of bacterial infections),
- Carbamazepine (used in the treatment of epilepsy).
- Adrenergic agonists/antagonists (such as certain types of medicine used to control blood pressure, nasal decongestants, blood pressure lowering medicines), opiate agonists/antagonists (used in the treatment of drug addiction), prostaglandin inhibitors (such as NSAID).
- Benzodiazepines and non-benzodiazepine hypnotics, (medicine used to induce sleep, such as zaleplon, zolpidem and zopiclone).
- Thioridazine (for the treatment of schizophrenia).
- Imipramine (for the treatment of depression).

VIGISOM with food, drink and alcohol

Take VIGISOM after you have eaten.

Alcohol should not be taken with VIGISOM, because it reduces the effectiveness of VIGISOM on sleep.

Pregnancy and breastfeeding

Do not take VIGISOM if you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby. Please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

VIGISOM may cause drowsiness or dizziness.

You should not engage in hazardous activities (such as driving or operating machinery) after taking VIGISOM.

It is not always possible to predict to what extent VIGISOM may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which VIGISOM affects them.

VIGISOM contains lactose monohydrate

VIGISOM contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take VIGISOM.

VIGISOM contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take VIGISOM

Do not share medicines prescribed for you with any other person.

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

The usual dose is one tablet at night, 1 - 2 hours before bedtime and after food. This dosage may be continued for up to thirteen weeks.

You should swallow the tablet whole. Do not crush or cut the tablet.

Your doctor will tell you how long your treatment with VIGISOM will last.

If you have the impression that the effect of VIGISOM is too strong or too weak, tell your doctor or pharmacist.

If you take more VIGISOM than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you take more VIGISOM than you should, you will feel drowsy

If you forget to take use VIGISOM

If you forget to take a dose, take another as soon as you remember, before going to sleep, or wait until it is time to take your next dose, at the normal time when it is due, then go on as before. Do not take a double dose to make up for forgotten individual doses.

If you stop taking VIGISOM

There are no known harmful effects if treatment is interrupted or ended early.

4. Possible side effects

VIGISOM can have side effects.

Not all side effects reported for VIGISOM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VIGISOM, please consult your health care provider for advice.

If any of the following happens, stop taking VIGISOM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to VIGISOM**.** You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Uncommon

- irritability, nervousness, restlessness, sleeplessness, abnormal dreams, nightmares, anxiety
- migraine, headache, lack of energy, restlessness associated with increased activity, dizziness, tiredness
- high blood pressure
- upper abdominal (stomach) 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, chest pain
- abnormal liver function and weight increase

Rare

- shingles
- reduced number of white blood cells in the blood
- high level of fatty molecules in the blood, 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

- visual impairment, blurred vision, watery eyes
- dizziness when standing or sitting, vertigo
- hot flushes
- acid reflux, stomach disorder, blistering in the mouth, tongue ulceration, upset stomach, vomiting, abnormal bowel sounds, wind, excess saliva production, bad breath, abdominal (stomach) discomfort, gastric disorder, inflammation of the stomach lining,
- eczema, skin rash, hand dermatitis, itchy rash, psoriasis, nail disorder
- arthritis, muscle spasm, neck pain, night cramps
- passing large volumes of urine, presence of red blood cells in the urine, urinating during the night
- increased duration of erection that might be painful, inflammation of the prostate gland
- tiredness, pain, thirst
- increased liver enzymes, abnormal blood electrolytes and abnormal laboratory tests.

Frequency not known

- hypersensitivity reaction, swelling of mouth or tongue, swelling of the skin
- abnormal milk secretion

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions & Quality Problem Reporting Form", found online under SAHPRA's publications:

https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf.

By reporting side effects, you can help provide more information on the safety of VIGISOM.

5. How to store VIGISOM

Store all medicines out of reach of children.

- Store at or below 25 °C
- Store in the original package
- Protect from light
- Do not use after the expiry date stated on the carton

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VIGISOM contains

- The active substance is melatonin. Each prolonged-release tablet contains 2 mg melatonin.
- The other ingredients are ammonia methacrylate copolymer type B, calcium hydrogen phosphate dehydrate, lactose monohydrate, magnesium stearate, silica colloidal anhydrous, talc
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What VIGISOM looks like and contents of the pack

VIGISOM prolonged-release tablets are white to off-white, round, biconvex tablets, with no imprint or break-line.

The tablets are packed in white opaque PVC/PVdC/aluminium blisters. One blister strip containing 20, 21 or 30 tablets are packed in a cardboard carton.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Included in pack.