Imovane®

zopiclone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Imovane.

It does not contain all the available information. 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 Imovane 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.

What Imovane is used for

Imovane is used to help people over 18 years of age with sleeping difficulties, also called insomnia. It can help you fall asleep and to reduce the number of times you wake up during the night. It is used for short term treatment (2-4 weeks) of insomnia. It is not recommended for use for more than 4 weeks at a time.

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

Ask your doctor if you have any questions about why Imovane has been prescribed for you.

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

Before you take it

When you must not take it

Do not take Imovane if you have:

- been drinking alcohol or you believe that you may have alcohol in your bloodstream
- sleep apnoea (a condition where you temporarily stop breathing while you sleep)
- myasthenia gravis (a condition in which the muscles become weak and tire easily)
- severe liver problems
- acute and/or severe lung problems
- had a stroke
- ever experienced sleep-walking or other unusual behaviour (such as driving, eating, making a phone call or having sex etc.) while not being fully awake after taking Imovane

Do not take Imovane as a long term treatment

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

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not give Imovane to children or adolescents.

There is no experience with its use in children or adolescents.

Do not take it if you are pregnant or intend to become pregnant.

It may affect your developing baby if you take it during pregnancy. Your doctor will discuss the risks and benefits of taking it if you are pregnant.

Do not take it if you are breastfeeding or planning to breastfeed.

Imovane passes into breast milk and there is a possibility your baby may be affected. Your doctor will discuss the risks and benefits of using it if you are breastfeeding or planning to breastfeed.

Do not take Imovane after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take Imovane if the packaging is damaged or shows signs of tampering.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- **any of the ingredients listed at the end of this leaflet**
- **any other substances such as foods, dyes or preservatives**

Tell your doctor if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Imovane is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of taking it if you are pregnant.

Tell your doctor if you are breastfeeding or planning to breastfeed.

Your doctor will discuss the risks of taking it if you are breastfeeding or planning to breastfeed.

Tell your doctor if you have any problems with your breathing or if you often snore while you are asleep.

Tell your doctor if you have ever been addicted to alcohol or any drug or medicine, or if you have ever suffered from a mental illness. If you have, you may be at risk of getting into a regular pattern or habit of taking Imovane.

Tell your doctor if you ever had a history of sleep-walking or other unusual behaviour (such as driving, eating, making a phone call, or having sex etc.) while not being fully awake after taking Imovane.

Imovane may cause sleep walking or other unusual behavior (such as driving, eating, making a phone call, or having sex etc.) while not being fully awake, some of which have been associated with serious injuries and death. The next morning, you may not remember that you did anything during the night. These activities may occur whether or not you drink alcohol or take other medicines that make you drowsy with Imovane. If you experience any of the above, stop the treatment with Imovane immediately and contact your doctor or health-care provider.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- **thyroid problems**
- **depression, psychosis or schizophrenia**
- **epilepsy**
- **addiction to drugs or medicines**

Tell your doctor if you plan to have surgery.

If you have not told your doctor or pharmacist about any of the above, tell them before you take Imovane.

Taking other medicines

You must tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food store.

Some medicines may interfere with the absorption of Imovane. These include:

- medicines to treat depression, anxiety and mental illness
- St John's wort, (hypericum), a herbal remedy for depression
- other medications which may cause drowsiness
- benzodiazepines (medicines used as sedatives or to treat anxiety)
- pain relievers, such as opioids or narcotic analgesics
- alcohol, (ethanol), contained in some medicines eg cough syrups
- muscle relaxants
- antihistamines
- medicines used to treat epilepsy
- antiviral medication
- rifampicin, erythromycin or clarithromycin (medicines used to treat infections)
- ketoconazole or itraconazole (medicines used to treat fungal infections)

These medicines may be affected by Imovane or may affect how well it works. You may need to take different amounts of your medicine or different medicines. Your doctor or pharmacist will advise you.

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

How to take it

How much to take

Imovane should only be taken when you are able to get a full night's sleep (7 to 8 hours) before you need to be active again.

The standard adult dose of Imovane is one tablet just before you go to bed.

Imovane should be taken in a single intake and not readministered during the same night.

If you are over 65 years of age the dose is half a tablet taken just before you go to bed.

If you have a liver or kidney problem, the usual recommended dose is half a tablet taken just before you go to bed.

Your doctor may have prescribed a different dose.

Ask your doctor if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Imovane may not work as well.

Imovane should not be given to children or adolescents less than 18 years of age.

How to take it

Swallow the tablet with a full glass of water.

When to take it

Take Imovane immediately before you go to bed. Imovane should be taken as a single intake and not be readministered during the same night.

It helps put you to sleep quite quickly. If you take Imovane on an empty stomach it may work more quickly.

If you are not sure when to take it, ask your doctor or pharmacist.

How long to take it

Imovane should only be used for short periods (eg 2 to 4 weeks). Continuous long term use (i.e. longer than 4 weeks) is not recommended.

Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

If you forget to take it

If you forget to take the tablet before you go to bed, and you wake up late in the night or very early in the morning, do not take it.

You may have trouble waking at your normal time.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (In Australia call 13 11 26 or New Zealand call 0800 POISON, 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Imovane.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Imovane.

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

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

If you become pregnant while you are taking this medicine, stop taking it and tell your doctor or pharmacist immediately.

Things you must not do

Do not take more than the recommended dose unless your doctor tells you to.

This can increase the risk of side effects.

Do not give this medicine to anyone else, even if they have the same condition as you.

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.

This can increase the risk of side effects.

Things to be careful of

Because Imovane will make you sleepy, you should not operate dangerous machinery or drive motor vehicles for 12 hours after you take it. You should also be careful the next morning when you wake up.

Make sure you know how you react to Imovane before you drive a car or operate machinery. This is very important if you are taking other drugs that also make you drowsy.

Impairment can occur despite feeling fully awake, in absence of symptoms or if you are feeling better.

Be careful if you are over 65 and unwell or taking other medicines.

You may be more sensitive to some of the side effects of Imovane.

You should not drink alcohol while you are taking Imovane.

The effects of alcohol could be made worse while taking Imovane.

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor as soon as possible if you do not feel well while you are taking Imovane.

It helps most people with insomnia, but it may have unwanted side effects in some people.

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

- headaches
- dry mouth
- bitter taste in your mouth
- drowsiness

These are the most common side effects of this medicine.

Less common side effects include:

- heartburn
- nausea, vomiting and/or diarrhoea
- change in appetite
- stomach pain
- rash
- agitation
- depression
- confusion
- anxiety
- dizziness
- blurred vision
- impotence
- sleep walking or other unusual behaviours (such as driving, eating, making a phone call, or having sex etc.) while not being fully awake, some of which have been associated with serious injuries and death

Alcohol can increase the risk of sleep walking or other behaviours such as driving or eating food whilst asleep. This risk is also increased if you take more than the recommended dose.

Some sleep medicines may cause a short-term memory loss. When this occurs, a person may not remember what has happened for several hours after taking the medicine. This is usually not a problem since most people fall asleep after taking the medicine.

Sleep medicines should in most cases, be used only for short periods of time. If your sleep problems continue, consult your doctor.

Some medicines can cause dependence, especially when they are used regularly for longer than a few weeks. People who have been dependent on alcohol or other drugs in the past may have a higher chance of becoming addicted to sleep medicines. If you have been addicted to alcohol or drugs in the past, it is important to tell your doctor before starting Imovane.

If any of the following happen, stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- **swelling of the face, lips, mouth or throat, which may cause difficultly in swallowing or breathing**
- **hives**
- **fainting**

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

These side effects are very rare.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you feel you are becoming depressed, having suicidal thoughts or are experiencing changes in your behaviour.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some consumers.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

After taking it

Sometimes when medicines are stopped suddenly, after being used for a long time, withdrawal symptoms may occur. Symptoms of withdrawal may include abdominal and muscle cramps, vomiting and sweating.

In some cases your insomnia may appear worse for a short time; speak to your doctor if this occurs.

Tell your doctor if you have any problems when you stop taking Imovane.

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

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

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

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 windowsill.

Heat and dampness can destroy some medicines.

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 ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking it, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Imovane is an oval, film-coated white tablet with a break-line on one side.

Imovane is available in blister packs of 14 and 30 tablets. In Australia there is also a pack of 10 tablets.
** Not all pack sizes marketed.

Ingredients

Each tablet contains 7.5 mg of zopiclone as the active ingredient.

Inactive ingredients:

- calcium hydrogen phosphate dihydrate
- wheat starch (gluten)
- sodium starch glycollate
- lactose monohydrate
- magnesium stearate

Coating (Opadry white OY-S-38906):

- hypromellose
- titanium dioxide
- macrogol 6000

Manufacturer

Imovane is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Imovane is supplied in New Zealand by:

sanofi-aventis new zealand limited

Level 8, 56 Cawley St

Ellerslie, Auckland

This leaflet was prepared in March 2021

Australian Registration Number:

Imovane - AUST R 165934

® Registered Trademark

imovane-ccdsv12-cmiv14-12mar21