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 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 tired easily)
- severe liver problems
- acute and/or severe lung problems
- had a stroke

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 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.
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 behaviours
whilst asleep
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
difficulty 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 30 tablets. In Australia there is also a pack of 10 tablets.

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 October 2017

Australian Registration Number:

Imovane - AUST R 165934

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imovane-cedsv10-cmiv11-oct17