IMOVANE® TABLET

Zopiclone (7.5 mg)

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What Imovane is used for

Imovane is used for short term treatment of sleep problems (insomnia) such as:
- Difficulty falling asleep
- Waking in the middle of the night
- Waking too early
- Severe or upsetting sleep problems that are caused by your mood or mental health problems

Do not take Imovane as long-term treatment. Treatment should be as short as possible because the risk of dependence increases with the duration of treatment.

Ask your doctor for advice if you are unsure.

How Imovane works

Imovane tablets are sleeping pills (hypnotics) which work by acting on the brain to cause sleepiness.

Before you use Imovane

- When you must not use it

Do not take Imovane if you:
- are allergic (hypersensitive) to zopiclone or any of the other ingredients in the tablet (see section **Product Description**). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- have severe liver problems
- suffer from breathing problems whilst sleeping (sleep apnoea syndrome)
- suffer from severe muscle weakness (myasthenia gravis)
- have severe breathing problems

These tablets are not recommended for use in children and pregnant women.

- Before you start to use it

Warnings:
Anaphylaxis (severe allergic reaction) and angioedema (severe facial swelling) which can occur as early as the first time the product is taken.

Complex sleep-related behaviors which may include sleep-driving, making phone calls, preparing and eating food while asleep.

Check with your doctor or pharmacist before taking Imovane tablets if you:
- have any kidney or liver problems.
- have a history of mental illness (including depression and personality disorder).
- have or have ever had a history of or tendency to alcohol or drug abuse or personality disorders.
- you have been told you have an intolerance to some sugars (e.g. lactose).
- If you are pregnant or breastfeeding, or planning to become pregnant.
- You have recently taken Imovane or other similar medicines for more than four weeks.
- You have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- You feel you need to take more of Imovane to get the same level of symptom control, this may mean you are developing tolerance to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medication.

Taking this medicine regularly, particularly for a long time, can lead to physical dependence and addiction.

Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

Physical dependence and addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include:
· feeling anxious, shaky, irritable, agitated, confused or having panic attacks
· sweating
· headache
· faster heartbeat or uneven heartbeat (palpitations)
· lower level of awareness or problems with focusing or concentrating
· nightmares
· seeing or hearing things that are not real (hallucinations)
· being more sensitive to light, noise and touch than normal
· relaxed grip on reality
· numbness and tingling in your hands and feet
· aching muscles
· stomach problems.

Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Z-drugs should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of Z-drugs, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Other considerations
- *Tolerance* – if after a few weeks you notice that the tablets are not working as well as they did when first starting treatment, you should go and see

your doctor as an adjustment to your dosage may be required.
- *Dependence* – when taking this type of medicine there is a risk of dependence, which increases with dose and length of treatment. There is a greater risk in patients with a history of alcohol or drug abuse or personality disorders.
- *Withdrawal* – treatment should be gradually withdrawn. A transient syndrome whereby the symptoms that led to treatment with Imovane tablets recur in an enhanced form, may occur on withdrawal. It may be accompanied by other reactions including mood changes, anxiety and restlessness.
- *Amnesia* – Imovane tablets can cause memory loss. To reduce this risk you should ensure that you are able to have a full night of uninterrupted sleep.
- if you have had a clot in an artery of your brain (ischaemic stroke) which occurred within the last seven days.
- if you have kidney or liver disease.

Imovane contains:
- **Lactose**. This is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- **Sodium.** This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially sodium-free'.
- **Gluten**. This medicine contains only very low levels of gluten (from wheat starch) and is very unlikely to cause problems if you have coeliac disease. If you have wheat allergy (different from coeliac disease) you should not take this medicine. One 3.75 mg tablet contains no more than 3 micrograms of gluten. One 7.5 mg tablet contains no more than 6 micrograms of gluten.

- Taking other medicines
Tell your doctor or pharmacist if you are taking or have recently taken any other medicine including medicines obtained without a prescription.

Taking Imovane with an opioid medicine (medicine to relieve pain) can depress your central nervous system. Inform your doctor if you are currently taking any opioid medicine.

Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

Imovane tablets may influence the effect and/ or side effects of other medicines. If you see another doctor or go into hospital, particularly if you are having an operation under anaesthesia, tell the doctor which medicines you use.

The following medicines may increase the sedating effect of Imovane tablets:
- medicines to treat mental illness (antipsychotics)
- medicines to treat depression
- other sleeping pills
- medicines to treat anxiety and other tranquilisers
- narcotics (strong pain killers) e.g. codeine, morphine
- medicines used to treat epilepsy
- anaesthetics (used during surgery)
- antihistamine medicines which cause sleepiness
- erythromycin (an antibiotic to treat infections).

Taking Imovane with alcohol
Alcohol should not be consumed when taking Imovane tablets, as the sedating effect may be increased.

Please refer to your doctor or pharmacist for the complete list on interaction.

How to use Imovane
- How much to use
The usual dose is:
- *Adult*s: 7.5mg before going to bed.
- *Elderly, patients with liver disease and chronic breathing problem:* A lower dose of 3.75mg may be used initially. This dose may be increased to 7.5mg.
- *Patients with kidney disease:* Treatment should be started with a dose of 3.75mg.
- *Children:* not recommended.

- When to use it
Swallow the tablet with a full glass of water. The tablet should be taken immediately before going to bed.
It helps put you to sleep quite quickly.

- How long to use it
Treatment should be as short as possible. In general, it should not exceed 4 weeks including the withdrawal period. Your doctor will choose a withdrawal regime based on your individual needs.

- If you forget to use 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 use too much (overdose)
If you, (or someone else) swallow a lot of the tablets at the same time, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Do not go unaccompanied to seek medical help. If an overdose has been taken, you may become increasingly drowsy very quickly, with high doses probably leading to a coma.

While you are using it
- Things you must do
- Tell all the doctors, dentists and pharmacists who are treating you that you are taking Imovane.
- Always take Imovane tablets exactly as your doctor has told you. You should check with your doctor or pharmacist when you are not sure.
- 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 you doctor and dentist that you are taking this medicine.
- If you become pregnant while you are taking this medicine, stop taking it and tell you doctor or pharmacist immediately.
- If you plan to stop taking Imovane, treatment should be gradually withdrawn as the symptoms you are treated for will return more intense than before (rebound insomnia or sleeplessness). Also, anxiety,

restlessness and mood changes may occur. These effects will disappear in time.
- Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. This may occur over a period of weeks to months. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.If you stop taking Imovane suddenly, your sleep problems may come back, and you may get a 'withdrawal effect'. In rare cases fits (seizures) may also occur. If you have any further questions on the use of the medicine, ask your doctor or pharmacist.

- 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 yours.
- 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

Driving and using machines

Because Imovane will make you sleepy, you should not operate dangerous machinery or drive motor vehicles after you take it. You should 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 medicines that also make you drowsy.

Be careful if you are over 65 years and unwell or taking other medicines. You may be more sensitive to some of the side effects of Imovane.

Possible Side Effect

Like all medicines, Imovane can cause side effects, although not everybody gets them.

Stop taking Imovane and see a doctor or go to a hospital straight away if:
- You have an **allergic reaction.** The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

Tell your doctor as soon as possible if you have any of the following side effects:

Rare (affects 1 to 10 users in 10,000)
- Poor memory since taking Imovane (amnesia). By having 7-8 hours of uninterrupted sleep after taking Imovane, this is less likely to cause you a problem.
- Seeing or hearing things that are not real (hallucinations)
- Falling, especially in the elderly

Not known (frequency cannot be estimated from available data)
- Thinking things that are not true (delusions)
- Feeling low or sad (depressed mood)

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

Common (affects 1 to 10 users in 100)
- A mild bitter or metallic taste in your mouth or a dry mouth
- Feeling drowsy or sleepy
- Dry mouth

Uncommon (affects 1 to 10 users in 1,000)
- Feeling sick (nausea) or being sick (vomiting)
- Feeling dizzy or sleepy
- Headache
- Nightmares
- Feeling physically or mentally tired
- Agitation

Rare (affects 1 to 10 users in 10,000)
- Feeling confused
- Itchy, lumpy rash (urticaria)
- Feeling irritable or aggressive
- Reduced sex drive
- Difficulty breathing or being short of breath

Not known (frequency cannot be estimated from available data)
- Feeling restless or angry
- Feeling light headed or having problems with your coordination
- Double vision
- Moving unsteadily or staggering
- Muscular weakness
- Indigestion
- Dependence and addiction to Imovane
- Slower breathing (respiratory depression)
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- Mental problems such as poor memory
- Difficulty paying attention
- Disrupted normal speech
- Imovane may cause sleepwalking or other unusual behavior (such as driving, eating, making a phone call, or having sex etc.) while not being fully awake.
- Delirium (a sudden and severe change in mental state that can cause a combination of confusion, disorientation and/or attention deficit)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my *[Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]*

Storage and Disposal of Imovane

- Storage
- Keep out of the reach and sight of children.
- Store below 30°C
- Do not use Imovane after the expiry date which is stated on the product packaging. The expiry date refers to the last day of that month.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Imovane is an oval, white film-coated tablet with a break-line on one side. Imovane is available in blister packs of 14, 20 tablets.

- Ingredients:

- *Active ingredient:* zopiclone. Each tablet contains 7.5mg of zopliclone
- *Inactive ingredients:* lactose, calcium hydrogen phosphate, wheat starch, sodium starch glycolate, magnesium stearate.
  Film coating: hypromellose, titanium dioxide (E171), macrogol 6000.

- MAL Number:

MAL19900140ARZ

Manufacturer

Opella Healthcare International SAS
56 Route de Choisy,
60200 Compiegne, France

Product Registration Holder

Sanofi-aventis (Malaysia) Sdn. Bhd.
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Date of revision

Oct 2026(UK PIL Nov 2025)

Serial number

NPRA (R1/3) 14092021/160