

# IMOVANE<sup>®</sup> TABLET

Zopiclone (7.5 mg)

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## What Imovane is used for

Imovane may be used for short term treatment of difficulties in falling asleep, waking up at night or early in the morning or difficulty in sleeping.

## 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.

### - 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.
- 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.

#### *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- *Withdrawal* – treatment should be gradually withdrawn.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.

### - 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.

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:

- *Adults*: 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 your doctor and 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.
- 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.

- 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.

**Side Effect**

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.

**If you experience the following rare, but very serious side effect, stop taking Imovane tablets and tell your doctor immediately or contact the casualty department at your nearest hospital:**

- **skin rash, swelling of the face, lips, tongue or throat, difficulty breathing, swallowing, light headedness, or lack of co-ordination.**

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. However these side effects are very rare.

**Tell your doctor or pharmacist if any of the following side effects occur or worsen:**

- *Effects on the nervous system:* headache, dizziness, drowsiness, irritability, aggressiveness, confusion, depression, amnesia, hallucinations or nightmares.
- *Others:* sometimes sleeplessness has occurred on stopping the tablets, usually following prolonged use.

If any of the side effects get worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers →Reporting)

### **Storage and Disposal of Imovane**

#### - Storage

- Keep out of the reach and sight of children.
- Store below 25°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 20 tablets.

#### - Ingredients:

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

#### - MAL Number:

MAL19900140A

### **Manufacturer**

Sanofi Winthrop Industrie  
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### **Product Registration Holder**

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