

Imovane

Film-coated Tablets 7.5 mg

Composition:

Each tablet contains: Zopiclone 7.5 mg

For information about inactive and allergenic ingredients in the preparation: see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read this leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not intended for children and adolescents under 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Imovane is intended for treatment of the following conditions of severe sleep disorders: a. transient insomnia. b. short-term insomnia.

Therapeutic group: Hypnotic and sedative from the cyclopyrrolone group.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to zopiclone or to any of the additional ingredients contained in the medicine (see section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- you suffer from a problem that causes severe muscle weakness (myasthenia gravis).
- you suffer from a problem in lung function (respiratory failure).
- you suffer from a problem in which you stop breathing for short periods at night (sleep apnoea).
- you suffer from severe liver problems.
- you are under the age of 18. The safety and efficacy of Imovane in children and adolescents aged less than 18 years have not been established.
- you have ever experienced sleepwalking or any other unusual behavior (such as driving, eating, making a phone call or having sex, etc.) while you are not fully awake after taking Imovane.

Do not take this medicine if any of the above conditions applies to you. If you are not sure, talk to your doctor or pharmacist before taking Imovane.

Special warnings regarding use of the medicine:

Before treatment with Imovane, tell your doctor if:

- you suffer from any liver problems (see also in section "Do not use the medicine if"). The doctor may need to give you a lower dose of Imovane.
- you suffer from any kidney problems. The doctor may need to give you a lower dose of Imovane.
- you suffer from mild breathing problems. The doctor will decide if you should receive Imovane (also see in section "Do not use the medicine if").
- you have had a mental disorder (including depression and personality disorder) or you have abused or have been dependent on alcohol or drugs.
- you have recently used Imovane or other similar medicines for more than 4 weeks.

Use of Imovane may lead to the development of abuse and/or physical and psychological dependence. The risk of dependence increases with dose and duration of treatment and is greater when Imovane is used for longer than 4 weeks, and in patients with a history of mental disorders and/or alcohol, illicit substance or drug abuse.

Drowsiness, breathing difficulties, coma and death may occur if Imovane is taken together with opioids. Imovane and opioids should only be used concomitantly when other treatment options are inadequate. Please tell your doctor about all the opioid medicines you are taking and closely follow your doctor's dosage recommendations.

- The medicine is not intended for treatment of depression.

Some studies have shown an increased risk of suicidal ideation, suicide attempt and suicide in patients taking certain sedatives and hypnotics, including this medicine. However, it has not been established whether this is caused by the medicine or if there may be other reasons. If you have suicidal thoughts, contact your doctor as soon as possible for further medical advice.

Before taking Imovane, it is important to make sure that you can have at least 7 to 8 hours of uninterrupted sleep, to help reduce the risk of some side effects (see section 4 - "Side effects").

Imovane may cause sleepwalking or other unusual behavior (such as driving, eating, making a phone call, or having sex etc.) while you are not fully awake. 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 effects, stop the treatment with Imovane immediately and contact your doctor or healthcare provider.

If you are not sure if any of the above conditions applies to you, talk to your doctor or pharmacist before taking Imovane.

Children and adolescents:

This medicine is not intended for children and adolescents under 18 years of age.

Tests and follow up:

Imovane can change the liver enzyme levels shown up in blood tests. This may indicate your liver is not working properly.

If you are going to have a blood test, it is important to tell your doctor that you are taking Imovane.

Drug interactions:

If you are taking, have recently taken, or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. This is because Imovane may affect the way some other medicines work. Also some medicines may affect the way Imovane works. Especially if you are taking: Imovane may increase the effect of the following medicines:

- Medicines for treatment of mental diseases (antipsychotics)
- Medicines for treatment of depression
- Medicines for treatment of epilepsy (anticonvulsants)
- Medicines used in surgeries (anesthetics)
- Medicines to calm or reduce anxiety or medicines for sleep problems (hypnotics)
- Medicines for treatment of hay fever, rashes or other allergies, that can make you sleepy (sedative antihistamines) such as chlorphenamine or promethazine
- Some medicines to relieve moderate to severe pain (narcotic analgesics) such as codeine, methadone, morphine, oxycodone, pethidine or tramadol

The following medicines can increase the chance of getting side effects when taken with Imovane. To make this less likely, your doctor may decide to lower the dosage of Imovane that you are taking:

- Some antibiotics, such as clarithromycin or erythromycin
- Some medicines for the treatment of fungal infections, such as ketoconazole and itraconazole
- Ritonavir (a protease inhibitor), for treatment of HIV infection
- Concomitant use of Imovane and opioids increases the risk of drowsiness, breathing difficulties, coma and death. Closely follow your doctor's dosage instructions.

The following medicines can make Imovane work less well:

- Some medicines for treatment of epilepsy such as carbamazepine, phenobarbital or phenytoin
- Rifampicin (an antibiotic), for treatment of infections
- St. John's wort (a herbal medicine), for treatment of mood swings and depression

Use of the medicine and alcohol consumption:

Do not drink alcohol while using Imovane. Alcohol can increase the effect of Imovane and make you sleep very deeply, so that you will not breathe properly or will have difficulty waking up.

Pregnancy and breast-feeding:

Pregnancy

Use of Imovane is not recommended during pregnancy. Before taking the medicine, consult your doctor if you are pregnant, think you might be pregnant, or are planning to have a baby.

If used during pregnancy, there is a risk that the baby is affected. Some studies have shown that there may be an increased risk of cleft lip and palate (sometimes called "harelip") in the newborn baby.

Reduced fetal movement and fetal heart rate variability may occur after taking Imovane during the second and/or third trimester of pregnancy. If Imovane is taken at the end of pregnancy or during labour, your baby may show muscle weakness, a drop in body temperature, difficulty feeding and breathing problems (respiratory depression).

If this medicine is taken regularly in the late stages of pregnancy, your baby may develop physical dependence and may be at risk of developing withdrawal symptoms such as agitation or shaking. In this case the newborn should be closely monitored during the postnatal period.

Breast-feeding

Do not take Imovane if you are breast-feeding or are planning to breast-feed. This is because small amounts may pass into mother's breast milk. If you are breast-feeding or planning to breast-feed, consult the doctor or pharmacist before using any medicine. Consult a doctor or pharmacist before taking any medicine if you are pregnant or breast-feeding.

Driving and operating machinery:

Like other medicines used for sleep problems, Imovane can cause slowing of normal brain functioning (central nervous system depression). The risk of psychomotor impairment, including driving ability, is increased if:

- you perform activities that require alertness within 12 hours of taking Imovane
- you take a higher dose than the recommended dose of Imovane
- you take Imovane while taking another central nervous system depressant, or another medicine that increases levels of Imovane in your blood, or while drinking alcohol

Do not engage in hazardous activities requiring complete alertness, such as driving or operating machinery, after taking Imovane, and in particular during the 12 hours after taking the medicine.

For more information about possible side effects which could affect your driving, see section 4 in this leaflet.

Important information about some of the ingredients of the medicine:

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, consult your doctor before starting to use this medicine.

- **Sodium:** This medicine contains less than 1 mmol sodium (23 mg) per tablet; that is to say, it is essentially "sodium-free".
- **Gluten:** This medicine contains only very low levels of gluten (from wheat starch) and is very unlikely to cause you problems if you have coeliac disease. If you have a wheat allergy (that is different from coeliac disease), do not take this medicine. One tablet contains no more than 6 micrograms of gluten.

3. HOW SHOULD YOU USE THE MEDICINE?

The treatment should be as short as possible and should not exceed 4 weeks (including the period of tapering off).

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

Adults:

The usual dosage is one Imovane tablet (7.5 mg) just before bedtime.

Elderly:

The usual starting dosage is half a tablet (3.75 mg) just before bedtime. Later, the dosage may be increased, if needed. Be careful and lean on something when getting out of bed!

Children and adolescents:

Imovane is not intended for use in children and adolescents under 18 years of age. The efficacy and safety of Imovane in children and adolescents aged less than 18 years have not yet been established.

Patients with liver, respiratory or kidney problems:

The usual starting dose is half a tablet (3.75 mg) just before bedtime.

Do not exceed the recommended dosage.

Duration of treatment:

The usual duration of treatment is two days to 3 weeks.

Method of administration:

- Swallow the medicine with water.
- Do not crush or chew the tablets.
- The tablet can be halved if a lower dose of 3.75 mg is required.
- Take the required dose of Imovane in a single intake, and do not take another dose during the same night.
- Take the preparation when you are in bed, just before bedtime, and make sure that you will be able to sleep 7-8 hours without interruption.

If you took a higher dosage or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Taking too much of Imovane is very dangerous. You may suffer from the following effects:

- Feeling drowsy, confused, sleeping deeply and even the possibility of falling into coma
- Floppy muscles (hypotonia)
- Feeling dizzy, lightheaded or faint. These effects are due to low blood pressure.
- Falling over or losing balance (ataxia)
- Shallow breathing or difficulty breathing (respiratory depression)

If you forget to take the medicine:

Imovane must only be taken at bedtime.

If you forgot to take the medicine at bedtime, do not take the medicine at any other time. Otherwise, you may feel drowsy, dizzy and confused during the day.

Never take two doses together instead of the forgotten dose!

If you stop taking the medicine:

Keep taking Imovane until your doctor tells you to stop. Do not stop taking Imovane suddenly, but tell your doctor if you want to stop the treatment. Your doctor will instruct you on how to stop the treatment. If you stop the treatment with Imovane suddenly, your sleep problems may come back and you may suffer from a "withdrawal effect".

If this happens, you may suffer from some of the effects listed below. Refer to a doctor immediately if you suffer from any of the following effects:

- Feeling anxious, shaky, irritable, agitated, confused or you have panic attacks
- Sweating
- Headache
- Faster or uneven heartbeat (palpitations)
- A lower level of awareness and problems with focusing or concentrating
- Nightmares, seeing or hearing things that are not real (hallucinations)
- Hypersensitivity to light, noise and touch
- Poor reality perception
- Numbness and tingling in the hands and feet
- Aching muscles
- Stomach problems

In rare cases, fits (seizures) may also occur.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Imovane may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Discontinue use and refer to a doctor or hospital immediately if:

- you suffer from an **allergic reaction** to Imovane. The signs may include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.

Refer to the doctor as soon as possible if you have any of the following side effects:

Rare side effects, effects that occur in 1-10 in 10,000 users:

- Memory impairment since taking Imovane (amnesia). You can reduce the chance of this effect by making sure that you have 7-8 hours of continuous and uninterrupted sleep after taking Imovane.
- Seeing or hearing things that are not real (hallucinations)
- Falling, especially in the elderly

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Thinking things that are not true (delusions)
- Feeling low or sad (depressed mood)

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

Common side effects, effects that occur in 1-10 in 100 users:

- A mild bitter or metallic taste in the mouth or a dry mouth
- Feeling drowsy or sleepy
- Dry mouth

Uncommon side effects, effects that occur in 1-10 in 1,000 users:

- Feeling sick (nausea) or being sick (vomiting)
- Feeling dizzy or sleepy
- Headache
- Nightmares
- Feeling physically or mentally tired
- Agitation

Rare side effects, effects that occur in 1-10 in 10,000 users:

- Feeling confused
- Itchy, lumpy rash (urticaria)
- Feeling irritable or aggressive
- Reduced sex drive
- Difficulty in breathing or shortness of breath

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Feeling restless or angry
- Feeling light-headed or having problems with your coordination
- Double vision
- Moving unsteadily or staggering
- Muscular weakness
- Indigestion
- Becoming dependent on Imovane
- Slower breathing (respiratory depression)
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paresthesia)
- 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 you are not fully awake.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month. Storage conditions: Store at a temperature that does not exceed 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Lactose (each tablet contains 31.575 mg lactose monohydrate) and traces of gluten (each tablet contains 60 mg wheat starch). Wheat starch; Calcium hydrogen phosphate dihydrate; Lactose monohydrate; Hypromellose; Sodium starch glycolate type A; Titanium dioxide; Macrogol 6000; Magnesium stearate.

What the medicine looks like and the contents of the package: Imovane tablets are white, elliptical-shaped, film-coated tablets, with a score line on one side.

Package size: 14, 20 tablets. Not all package sizes may be marketed.

This leaflet does not contain all the information about the preparation. If you have any questions or are uncertain about anything, please refer to the doctor.

License Holder and Importer and its address: sanofi-aventis Israel Ltd., 10 Beni Gaon Street, Netanya.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1011924581.