

Patient Information Leaflet (clean): 19 February 2020

SCHEDULING STATUS: S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

IMOVANE TABLETS

Zopiclone

Read all of this leaflet carefully before you start taking IMOVANE TABLETS.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- IMOVANE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT IMOVANE CONTAINS:

The active substance in each tablet is 7,5 mg zopiclone.

Other excipients are: Calcium hydrogen phosphate, lactose, magnesium stearate, sodium starch glycolate, wheat starch and the film-coating contains: hypromellose, macrogol 6000 and titanium dioxide.

Contains sugar (lactose): IMOVANE contains 31,6 mg lactose per tablet.

WHAT IMOVANE IS USED FOR:

IMOVANE belongs to the class of medicines called hypnotics. IMOVANE is used for the short-term treatment of sleeping difficulties (insomnia) in adults. (The duration of treatment

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must be as short as possible: from a few days to two weeks, with a maximum of not more than 4 weeks.)

BEFORE YOU TAKE IMOVANE:


Do not take IMOVANE if:

- you are hypersensitive (allergic) to IMOVANE (see Possible side effects) or to any of the other ingredients listed under: WHAT IMOVANE CONTAINS.
- you have severe muscle weakness (myasthenia gravis)
- your lungs do not work properly (respiratory failure)
- you have a problem where you stop breathing for short periods at night whilst sleeping (severe sleep apnoea)
- you have severe liver problems
- you are under the age of 18. IMOVANE should not be used in children and young adults aged less than 18 years
- you are pregnant or breastfeeding or planning to become pregnant
- you have been drinking alcohol or you believe that you may have alcohol in your bloodstream. This may enhance some effects of IMOVANE such as drowsiness or dizziness and your ability to drive may be at risk.

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

Tell your doctor or pharmacist before taking IMOVANE if:

- you suffer from mild breathing problems; your doctor will decide if you should receive IMOVANE (also see Do not take IMOVANE if)
- you are using opioids (e.g. pain killers such as codeine), please tell your doctor that you are using opioid medicines and follow your doctor's dosage recommendations

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closely. Taking IMOVANE together with opioids may cause dangerous side effects such as drowsiness, difficulties breathing, coma and death

- you have depression (including suicidal thoughts) or have had another mental illness in the past, IMOVANE may not be a suitable treatment and may make these conditions worse or mask it so that your doctor is not able to diagnose you properly
- you have a history of alcohol or drug abuse
- you have recently taken IMOVANE or other similar medicines for more than four weeks
- you do not feel you will ever be able to stop taking IMOVANE or other medicines used to treat sleep problems
- you have any liver problems (also see Do not use IMOVANE, above). Your doctor may need to give you a lower dose of IMOVANE
- you have any kidney problems. Your doctor may need to start your treatment with IMOVANE at a lower dose.

Take special care with IMOVANE:

- IMOVANE can depress your normal brain function leading to a slowing down of thought, drowsiness and reducing your physical movement, alertness and reactions. Do not operate dangerous machinery or drive motor vehicles for 12 hours after you have taken IMOVANE (see Driving and using machines, below).
- IMOVANE should be used only for short periods of time and should not be taken for longer than 4 weeks. If your sleep problems continue, consult your doctor so that the reason for your sleep problems can be investigated.
- The use of IMOVANE may lead to the development of abuse and dependence. The risk of dependence increases with higher doses and longer duration of treatment. The risk is greater when you use IMOVANE for longer than 4 weeks, if you have a

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history of mental disorders and/or alcohol or drug abuse. Before starting IMOVANE, tell your doctor if any of the above applies to you.

- Short-term memory loss may occur, especially when your sleep is interrupted or when you do not go to bed immediately after taking your IMOVANE tablet. When this occurs, you may not remember what has happened for several hours after taking IMOVANE. To reduce the possibility of memory loss, you should ensure that you retire for the night directly after taking the tablet and that you are able to have a full night's sleep (at least 7 to 8 hours of uninterrupted sleep).
- If you are over 65 and unwell or taking other medicines, you may be more sensitive to some of the side effects of IMOVANE – see Possible side effects.
- Sleep walking and other behaviours such as “sleep driving” have been reported (see Possible side effects).


Taking IMOVANE with food and drink:

Do not drink alcohol while you are taking IMOVANE. Alcohol can increase the effects of IMOVANE and make you sleep very deeply so that you do not breathe properly or have difficulty waking.

Pregnancy and Breastfeeding:

If you are pregnant, think you may be pregnant, planning to have a baby or you are breastfeeding your baby, please consult your doctor pharmacist or healthcare provider before taking IMOVANE.

The safety of IMOVANE during pregnancy and breastfeeding has not been established. If IMOVANE is taken during pregnancy your baby may have a low body temperature or breathing difficulties and show withdrawal symptoms after birth because of physical

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dependence. Therefore, IMOVANE should not be taken during pregnancy or breastfeeding (see Do not take IMOVANE, above).

Driving and using machinery:

IMOVANE causes drowsiness, impaired concentration and can also cause slowing of your normal brain function (central nervous system). The risk of psychomotor impairment (reducing your physical movement and reactions) including driving ability, is increased if:

- you take IMOVANE within 12 hours of performing activities that require mental alertness
- you take higher than the recommended dose of IMOVANE
- you take IMOVANE while already 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 mental alertness such as driving or operating machinery after taking IMOVANE and, in particular, during the 12 hours after taking your medicine.

For more information about possible side effects, e.g. drowsiness, which could affect your driving (see Possible side effects, below).

Important information about some of the ingredients of IMOVANE:

Lactose: IMOVANE tablets contain lactose (see What IMOVANE contains), which may have an effect on the glycaemic control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of galactose intolerance should not take IMOVANE.

Wheat starch: People with wheat allergy should not take IMOVANE. (Wheat allergy is not the same as Coeliac disease. IMOVANE can be taken by people with Coeliac disease.)

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Taking other medicines with IMOVANE:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following:

IMOVANE may increase the effect of the following medicines:


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

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

- Some antibiotics such as clarithromycin or erythromycin
- Some medicines for fungal infections such as ketaconazole and itraconazole
- Ritonavir (a protease inhibitor) - for HIV infections
- Concomitant use of IMOVANE and opioids increases the risk of drowsiness, difficulties breathing, coma and death (also see Tell your doctor or pharmacist before taking IMOVANE, above).

The following medicines can make IMOVANE work less well:

- Some medicines for epilepsy such as carbamazepine, phenobarbitone or phenytoin

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- Rifampicin (an antibiotic) - for infections
- St. John's Wort (a herbal medicine) - for mood swings and depression.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking IMOVANE, as this list may not be complete.

HOW TO TAKE IMOVANE:

Your treatment will be at the lowest recommended dose and as short as possible, usually for less than 4 weeks, and the doctor may reduce your dose near the end of your course. If you take IMOVANE longer than this, IMOVANE may not work as well, you may become dependent and you may have withdrawal symptoms when you stop.

- Do not share IMOVANE prescribed for you with any other person.
- Always take IMOVANE exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- Swallow your tablet whole with a small glass of water, do not crush or chew it.
- Take IMOVANE just before bedtime in a single intake and do not take it again during the same night.
- 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 usual adult dose is one IMOVANE tablet (7,5 mg) just before bedtime. This dose should not be exceeded.

IMOVANE should not be given to children and young adults under the age of 18.

Your doctor may have prescribed a lower dose, depending on your age and health status. Ask your doctor if you are unsure of the correct dose or if you have the impression that the

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effect of IMOVANE is too strong or too weak. Your doctor will tell you exactly how much to take. This dose should not be exceeded.

If you take more IMOVANE than you should:

Taking too much IMOVANE can be very dangerous and may lead to shallow breathing or difficulty breathing and falling into a coma. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take the medicine pack with you.

If you forget to take IMOVANE:

IMOVANE must only be taken at bedtime. If you forget to take your tablet at bedtime, then you should not take it at any other time, otherwise you may feel drowsy, dizzy and confused during the day.


Do not take a double dose to make up for a forgotten tablet.

Effect when treatment with IMOVANE is stopped:

When you stop using IMOVANE your doctor will advise you to slowly taper down your dosage.

If you stop taking IMOVANE suddenly, your sleep problems may come back and you may get a "withdrawal effect". If this happens you may get some of the effects listed below. See a doctor straight away if you get any of the following effects:

- feeling anxious, tension, restless, shaky, irritable, agitated, confused or having panic attacks
- sweating
- headache
- faster heartbeat or uneven heartbeat (palpitations)
- a lower level of awareness and problems with focusing or concentrating

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- 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
- in very rare cases fits (seizures) may also occur.

In some cases, your insomnia or inability to sleep may appear worse for a short time (Rebound insomnia). Tell your doctor if this occurs or if you have any other problems when you stop taking IMOVANE.

POSSIBLE SIDE EFFECTS:

IMOVANE can have side effects.

Not all side effects reported for IMOVANE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking IMOVANE, please consult your doctor, pharmacist or other healthcare professional for advice.


If any of the following happens, stop taking IMOVANE and tell your doctor or pharmacist immediately or go to the casualty department of your nearest hospital:

Less frequent:

- you have an allergic reaction. The signs may include: a rash, swelling of your lips, face, throat or tongue, swallowing or breathing problems, fainting and collapse.

These are all 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.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

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Less frequent:

- 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.

Frequency unknown:

- thinking things that are not true (delusions).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you have any of the following:

Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. However, check with your doctor if any of the following side effects continue or are bothersome:

Frequent:

- a mild bitter or metallic taste in your mouth or a dry mouth
- feeling drowsy or sleepy
- dry mouth.

Less frequent:

- feeling confused
- nightmares
- agitation
- feeling irritable or aggressive
- feeling sick (nausea) or vomiting
- feeling dizzy
- headache
- feeling physically or mentally tired
- hives, rash and itching

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- reduced sex drive
- difficulty breathing or being short of breath
- change in blood tests (increase of liver enzymes in the blood).

Frequency unknown:

- feeling restless or angry
- 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 (paraesthesia)
- mental problems such as poor memory
- difficulty paying attention
- disrupted normal speech.

Sleep-Driving and other strange behaviour

Sleep walking and other behaviours such as “sleep driving”, preparing and eating food, or making phone calls, with no memory of these events, may occur while you are asleep after taking IMOVANE. Using alcohol and certain other medicines or using higher doses than you should, could increase the risk of such behaviours. Tell your doctor immediately if this occurs.

Withdrawal symptoms on discontinuation of treatment

See Effect when treatment with IMOVANE is stopped, above.

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If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF IMOVANE:

Store all medicines out of reach of children.

Store at or below 25 °C and protect from light.

Store in the original container. Do not remove tablets from the blister before ready to use.

Do not use your tablets after the expiry date shown on the container.

Return all unused medicine to your pharmacist.

PRESENTATION OF IMOVANE:

IMOVANE is presented in blister packs of 30 tablets.

IDENTIFICATION:

IMOVANE tablets are white, film-coated, elliptical tablets, with a breakline on one side.

REGISTRATION NUMBER:

T/2.2/104

NAME AND BUSINESS ADDRESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:


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