IMREST®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking IMREST?

IMREST contains the active ingredient zopiclone. IMREST is used to help people over 18 years 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 (7-14 days) of insomnia.

For more information, see Section 1. Why am I taking IMREST? in the full CMI.

2. What should I know before I take IMREST?

Do not use if you have ever had an allergic reaction to IMREST or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take IMREST? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with IMREST and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take IMREST?

- IMREST 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 IMREST is one tablet just before you go to bed.

More instructions can be found in Section 4. How do I take IMREST? in the full CMI.

5. What should I know while taking IMREST?

Things you should do	• Remind any doctor, dentist or pharmacist who you visit that you are taking IMREST. • If you become pregnant while you are taking this medicine, stop taking it and tell your doctor or pharmacist immediately.
Things you should not do	• Do not take more than the recommended dose unless your doctor tells you.
Driving or using machines	• Because IMREST 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.
Drinking alcohol	• You should not drink alcohol while you are taking IMREST. • The effects of alcohol could be made worse while taking IMREST.
Looking after your medicine	• Follow the instructions on the carton on how to take care of your medicine properly. • Keep your tablets in the blister pack until it is time to take them. • Store below 25°C, in a cool dry place away from moisture, heat or sunlight. • Keep it where young children cannot reach it.

For more information, see Section 5. What should I know while taking IMREST? in the full CMI.

6. Are there any side effects?

Common side effects include headache, bitter taste in your mouth, dry mouth and drowsiness. Serious side effects include allergic reaction symptoms such as swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing. Other serious side effects include fainting, depression, suicidal thoughts or changes in your behaviour.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

IMREST®

Active ingredient(s): *zopiclone*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking IMREST. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking IMREST.**

Where to find information in this leaflet:

1. Why am I taking IMREST?
2. What should I know before I take IMREST?
3. What if I am taking other medicines?
4. How do I take IMREST?
5. What should I know while taking IMREST?
6. Are there any side effects?
7. Product details

1. Why am I taking IMREST?

IMREST contains the active ingredient zopiclone.

IMREST belongs to a class of medications called sedative-hypnotics.

IMREST is used to help people over 18 years of age 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 (7-14 days) of insomnia.

Your doctor, however, may prescribe IMREST for another purpose. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

2. What should I know before I take IMREST?

Warnings

Do not take IMREST if you:

- are allergic to zopiclone, 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.

  Always check the ingredients to make sure you can take this medicine.
- have been drinking alcohol or you believe that you may have alcohol in your bloodstream
- have sleep apnoea (a condition where you temporarily stop breathing while you sleep)
- have myasthenia gravis (a condition in which the muscles become weak and tire easily)
- have severe liver problems
- have acute and/or severe lung problems
- have had a stroke
- have ever experienced sleep walking or other unusual behaviour (such as driving, eating, making a phone call or having sex etc.) while not being fully awake after taking IMREST.
- **Do not take IMREST as a long-term treatment.**

  Treatment should be as short as possible, because the risk of dependence increases with the duration of treatment.
- **Do not take IMREST if the packaging is damaged or shows signs of tampering.**
- **Do not give IMREST to children or adolescents.**
- **Do not take it if you are pregnant or intend to become pregnant.**
- **Do not take it if you are breastfeeding or planning to breastfeed.**

Check with your doctor if you:

- take any other medicines for any other condition.
- have allergies to any of the ingredients listed at the end of this leaflet or any other substances such as foods, dyes or preservatives.
- have any problems with your breathing or if you often snore while you are asleep.
- have ever been addicted to alcohol or any drug or medicine, or if you have ever suffered from a mental disorder. If you have you may be at risk of getting into a regular pattern or habit of taking IMREST.
- ever had a history of sleep-walking or other unusual behaviour (such as driving, eating, making a phone call, or having sex etc.) while not being fully awake after taking IMREST.

IMREST may cause sleep-walking or other unusual behaviour (such as driving, eating, making a phone call, or having sex etc.) while not being fully awake, some of which have been associated with serious injuries and death. 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 IMREST. If you experience any of the above, stop the treatment with IMREST immediately and contact your doctor or health-care provider.

IMREST can cause drowsiness and a decreased level of consciousness. Keep IMREST in a safe place to protect it from theft as it may be used illicitly for criminal action (which could be dangerous) particularly in combination with alcohol, when given without knowledge of the victim. Never give your IMREST to anyone else because it may harm them.

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 IMREST.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

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 if you are pregnant.

Do not take it if you are breastfeeding or planning to breastfeed.

IMREST passes into breast milk and there is a possibility your baby may be affected. Your doctor will discuss the risks and benefits of taking it if you are breastfeeding or planning to breastfeed.

Use in children

- **Do not give IMREST to children or adolescents.**
- There is no experience with its use in children or adolescents.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with the absorption of IMREST. 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 e.g. 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 IMREST 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 IMREST.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect IMREST.

4. How do I take IMREST?

How much to take

- IMREST 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 IMREST is one tablet just before you go to bed.
- IMREST 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, IMREST may not work as well.
- **IMREST should not be given to children or adolescents less than 18 years of age.**

When to take IMREST

- Take IMREST immediately before you go to bed. IMREST 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 IMREST 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 IMREST

- IMREST should only be used for short periods (e.g. 7-14 days). Continuous long-term use is not recommended.
- Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

How to take IMREST

- Swallow the tablet with a full glass of water.

If you forget to take IMREST

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.

After taking IMREST

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 IMREST.

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.

If you take too much IMREST

If you think that you or anyone else may have taken too much IMREST, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26)
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking IMREST?

Things you should do

- Tell all the doctors, dentists and pharmacists who are treating you that you are taking IMREST.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking IMREST.
- 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 should 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 your medicine to anyone else, even if they have the same condition as you.**
- **Do not take IMREST 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.

Driving or using machines

Because IMREST 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 IMREST before you drive a car or operate machinery. This is very important if you are taking other drugs that also make you drowsy.

Impairment can occur despite feeling fully awake, in absence of symptoms or if you are feeling better.

Use in Elderly (over 65 years)

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 IMREST.

Drinking alcohol

You should not drink alcohol while you are taking IMREST.

The effects of alcohol could be made worse while taking IMREST.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

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.

Store below 25°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
General • headaches • dry mouth • bitter taste in your mouth • drowsiness	**Speak to your doctor if you have any of these less serious side effects and**

Less serious side effects	What to do
These are the most common side effects on this medicine. Less common side effects include: **Gut related** • heartburn • nausea, vomiting and/or diarrhoea • change in appetite • stomach pain **General** • rash • blurred vision **Sexual health** • impotence **Central nervous system-related** • agitation • depression • confusion • anxiety • dizziness • sleep walking or other unusual behaviours (such as driving, eating, making a phone call, or having sex etc.) while not being fully awake, some of which have been associated with serious injuries and death • delirium (a sudden change in mental state that can cause a combination of confusion disorientation and/or attention deficit)	**they worry you.**

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 sleep 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 IMREST.

Serious side effects

Serious side effects	What to do
Allergy related • swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing • hives **General** • fainting **Central nervous system-related** • suicidal thoughts or are experiencing changes in your behaviour	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

These are very serious side effects. If you have them, you may have had a serious allergic reaction to IMREST. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What IMREST contains

Active ingredient (main ingredient)	Zopiclone 7.5 mg
Other ingredients (inactive ingredients)	• lactose • calcium hydrogen phosphate • maize starch • povidone • magnesium stearate • Opadry White Y-1-7000 (ID 1475)
Potential allergens	lactose

Do not take this medicine if you are allergic to any of these ingredients.

What IMREST looks like

IMREST 7.5 mg tablets are white, film coated, oval tablets embossed with "Z" breakline "Z" on one side and "7.5" on the other. (AUST R 99794).

Who distributes IMREST

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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