

Imrest

contains the active ingredient zopiclone

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Imrest.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Imrest against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Imrest is used for

Imrest is used to treat short-term insomnia (trouble sleeping).

Imrest is thought to work by:

- * reducing the time needed to fall asleep
- * increasing the duration of sleep
- * decreasing the number of times that you awake during the night.

In general, Imrest should only be taken for short periods only (2 to 4 weeks). Continuous long-term use is not recommended as it may lead to physical or psychological dependence.

Ask your doctor if you have any questions about why Imrest has been prescribed for you.

Your doctor may have prescribed Imrest for another reason.

Imrest is available only with a doctor's prescription.

Before you take Imrest

When you must not take it

Do not take Imrest if you are allergic to any other medicines containing zopiclone or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take Imrest if you have:

- * myasthenia gravis, a condition in which the muscles become severely weak and tire easily
- * severe lung or airway problems
- * sleep apnoea, a condition where you temporarily stop breathing whilst asleep
- * had a stroke
- * severe liver problems.

Do not give Imrest to children.

Safety in children and teenagers under 18 years of age has not been established.

Do not take Imrest if the expiry date (EXP.) printed on the pack has passed.

If you take this medicine after the

expiry date, it may not work as well or it may have an entirely unexpected effect.

Do not take Imrest if the packaging shows signs of tampering or the tablets do not look quite right.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Imrest may affect your developing baby if you take it during pregnancy. Your doctor will discuss the risks and benefits of taking Imrest during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Imrest passes into breast milk and may affect your baby. Imrest is not recommended for use while breastfeeding.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- * chronic lung or breathing problems
- * thyroid problems
- * kidney problems
- * severe liver problems
- * mental problems such as depression, psychosis, schizophrenia

- * epilepsy (fits or convulsions)
- * drug or alcohol dependence.

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you drink alcohol regularly.

Alcohol may increase the effects of Imrest.

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you start taking Imrest.

Taking other medicines

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

Some medicines may be affected by Imrest, or may affect how well it works. These include:

- * other sleeping tablets, sedatives or tranquillisers
- * medicines for depression and anxiety
- * medicines for epilepsy, including carbamazepine, phenytoin
- * muscle relaxants
- * antihistamines
- * certain strong pain relievers, eg: codeine
- * certain antibiotics such as erythromycin, clarithromycin, rifampicin
- * antifungals such as ketoconazole, itraconazole
- * ritonavir, an anti-viral used in the treatment of AIDS infections
- * St John's wort, a herbal remedy.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be

careful with or avoid while taking Imrest.

How to take Imrest

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

The usual dose is one tablet (7.5 mg) just before you go to bed.

Elderly people and people with liver problems may need smaller doses.

Your doctor may advise you to take a different dose. This depends on your condition and whether or not you are taking any other medicines.

How to take it

Swallow the tablet with a glass of water.

Imrest tablets can be broken in half along the breakline if your doctor has prescribed half a tablet.

When to take it

Imrest should be taken when you go to bed. Only take Imrest if you feel you will need help sleeping.

Imrest can be taken with or without food.

How long to take it for

Keep taking Imrest for as long as your doctor tells you to.

Usually, Imrest is taken for short periods only (for example 2 to 4 weeks). Continuous long-term use is not recommended unless advised by your doctor. The use of Imrest long-term may lead to dependence on the medicine.

If you forget to take it

If you forget to take Imrest before you go to bed and you wake up late in the night or early in the morning, do not take Imrest as you may have trouble waking in the morning or experience morning drowsiness.

Take the next dose the following night when you are meant to.

If you are not sure what to do or have any questions, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Imrest. Do this even if there are no signs of discomfort or poisoning.

If you take too much Imrest, you may feel drowsy, lack energy and coordination and feel unsteady when walking.

While you are taking Imrest

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Imrest.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Imrest.

Tell your doctor if you think Imrest is not helping you to sleep.

If you become pregnant while taking Imrest, tell your doctor.

If you plan to have surgery (that needs a general anaesthetic), including dental surgery, tell your doctor or dentist that you are taking Imrest.

Things you must not do

Do not take Imrest for a longer time than your doctor has prescribed.

Imrest should be taken for short periods only (for example 2 to 4 weeks) unless advised otherwise by your doctor.

Do not stop taking Imrest, or change the dose, without checking with your doctor.

Stopping Imrest suddenly may cause some unwanted effects such as anxiety, tremor, sweating, headache, confusion and palpitations. For patients on prolonged treatment, insomnia may recur if Imrest treatment is stopped abruptly. Your doctor will gradually reduce the amount of Imrest you are taking before stopping completely.

Do not suddenly stop taking Imrest if you suffer from epilepsy.

Stopping this medicine suddenly may make your epilepsy worse.

Do not use Imrest to treat any other conditions unless your doctor tells you to.

Do not give Imrest to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Imrest affects you.

Imrest may cause drowsiness or loss of coordination in some people. Even though you take Imrest at night, you may still be affected the next day. Make sure you know how Imrest affects you before you drive a car, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while taking Imrest.

Your tolerance for alcohol may be lower than usual when taking Imrest. Combining Imrest and alcohol may cause unwanted side effects. Your doctor may suggest that you avoid

alcohol or reduce the amount of alcohol you drink while you are taking Imrest.

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Imrest.

Imrest helps most people with insomnia, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age, you may have an increased chance of getting side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

Common side effects

- * bitter taste, dry mouth
- * drowsiness, fatigue
- * headache.

Less common side effects

- * heartburn, nausea, vomiting, stomach pains, bad breath
- * change in appetite
- * constipation, diarrhoea
- * change in frequency of urination
- * impotence
- * sleep walking, or similar inappropriate behaviours such as

'sleep driving', preparing and eating food, or making phone calls whilst half asleep

- * blurred vision.

The above list includes the milder side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- * agitation, anxiety, depression
- * loss of memory
- * skin rash or itch
- * aggression
- * confusion, dizziness
- * unusual tiredness or weakness
- * lack of coordination
- * nightmares
- * fast or irregular heartbeat (elderly patients).

The above list includes serious side effects which may require medical attention. These side effects are not common.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

After taking Imrest

Storage

Keep Imrest where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they will not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25 degrees C.

Do not store Imrest or any other medicine in the bathroom or near a sink.

Do not leave Imrest in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Imrest, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Medical Information

Phone: 1800 028 365

Australian registration number:

Imrest - AUST R 99794, 99797

This leaflet was prepared on
31 May 2007.

Product description

What it looks like

Imrest is an oval, white, film-coated tablet marked "Z|Z" on one side and "7.5" on the other. The tablets are scored.

Each pack contains 30 tablets.

Ingredients

The active ingredient in Imrest is zopiclone. Each tablet contains 7.5 mg of zopiclone.

The tablets also contain the following inactive ingredients:

- * lactose anhydrous
- * calcium hydrogen phosphate anhydrous
- * maize starch
- * povidone
- * magnesium stearate
- * Opadry White Y-1-7000.

The tablets are gluten free.

Supplier

Imrest is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au