

PACKAGE LEAFLET

Package leaflet: Information for the patient

Insomniger 10 mg and 20 mg tablets temazepam

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again
- If you have further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Insomniger is and what it is used for
2. What you need to know before you take Insomniger
3. How to take Insomniger
4. Possible side effects
5. How to store Insomniger
6. Contents of the pack and other information.

1. What Insomniger is and what it is used for

Insomniger belongs to a group of medicines called benzodiazepines or hypnotics.

Benzodiazepines are used to make you feel less anxious, they can also be used to make you feel sleepy, relax your muscles and stop or prevent fits. Insomniger can be used for the following:

- difficulty sleeping (insomnia), when your lack of sleep is causing you a lot of distress
- to be given before minor surgery and other similar procedures (pre-medication) to make you feel more relaxed (or less anxious).

2. What you need to know before you take Insomniger

Do not take Insomniger:

- if you are allergic to temazepam, or any other benzodiazepine medicine (such as diazepam or nitrazepam), or any of the other ingredients in this medicine (listed in section 6)
- if you suffer from long term fatigue and muscle weakness (myasthenia gravis)
- if you suffer from irregular breathing whilst asleep (sleep apnoea syndrome)
- if you have severe lung or liver problems
- if you have a genetic disease called spinocerebellar ataxia (SCA)
- if you have a dependence on alcohol or drugs (including sedatives and painkillers)
- if you are under 18 years old.

Warnings and precautions

Talk to your doctor or pharmacist before taking Insomniger:

- if you have a history of alcohol or drug abuse
- if you have liver or kidney problems
- if you have lung problems

- if you are suffering from depression or anxiety associated with depression
- if you find that you need to get up regularly during the night, for example to go to the bathroom
- if you have a personality disorder such as schizophrenia
- if you have a history of convulsions, fits or seizures.

Other medicines and Insomniger

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, or the following:

- other medicine to help you get to sleep e.g. nitrazepam, chloral hydrate
- any other medicine to treat nervousness, feeling anxious, or for depression
- any medicine to treat severe mental health illness
- disulfiram used in the treatment of alcohol dependence
- strong pain killers e.g. morphine
- antihistamines that cause drowsiness, normally used to treat allergies but may also be used to help you sleep
- any medicine to treat Parkinson's disease
- medicine to treat convulsions or fits (epilepsy)
- medicine to treat blood pressure or irregular heartbeat
- rifampicin, a medicine used to treat bacterial infections
- any other medicine that can make you feel drowsy or less alert as temazepam may increase this effect
- the contraceptive pill.

Concomitant use of temazepam and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe temazepam together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

If you are going to have an operation or need an anaesthetic, tell the doctor or dentist that you are taking Insomniger. If you take Insomniger before a minor operation or procedure it is important that you have someone to accompany you home.

Insomniger with alcohol

Do not drink alcohol while you are taking Insomniger as it may make you feel more sleepy.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.

Do not take Insomniger if you are pregnant, might become pregnant or are breast-feeding. However, if your doctor has decided that you should receive this medicine during late pregnancy or during labour, your baby might have a low body temperature, floppiness, and breathing

difficulties when born. If this medicine is taken regularly in late pregnancy, your baby may develop withdrawal symptoms.

If taken whilst breast-feeding, temazepam may be present in the breast milk.

Driving and using machines

Insomniger may make you sleepy or affect your concentration, memory or how your muscles work. This may affect your ability to drive or operate machinery. Do not drive or operate machinery until you are sure you are not affected.

Insomniger contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Insomniger

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

If you take Insomniger **for sleeping difficulties (insomnia)** your doctor will usually give you Insomniger for a maximum of 4 weeks, this will include a period of time when your dose is reduced slowly before you stop taking Insomniger. Reducing your dose slowly will help to reduce the risk of side effects from withdrawal of the product.

It is also important that you are able to have 7-8 hours of uninterrupted sleep after taking your tablet. If you are late getting to bed or your sleep is interrupted you may suffer from unwanted side effects such as memory loss or feeling drowsy. You may also behave strangely or differently to how you would normally behave. Also, as this medicine is a muscle relaxant, people who have taken Insomniger and get up during the night are at greater risk of falling and fracturing their hip. The risk of this occurring is greater in the elderly.

At high doses taken for a long period of time, it is possible that you may become dependent on your medicine. If this happens to you, you must speak to your doctor.

Adults

Insomnia

The recommended dose is 10 mg or 20 mg half an hour before going to bed. In certain cases your doctor may increase the dose to 30 mg or 40 mg.

Pre-medication

The recommended dose is 20-40 mg, half an hour to one hour before your procedure.

Elderly

Insomnia

Older people usually require smaller doses of 10 mg half an hour before going to bed, but in certain cases the dose may be increased to 20 mg.

Pre-medication

The recommended dose is 10-20 mg, half an hour to one hour before your procedure.

Children and adolescents

Insomniger is **not** recommended for use in children or adolescents younger than 18 years of age.

People with breathing difficulties or liver problems

If you have a long-term problem with your breathing or problems with your liver your doctor may recommend that you take a lower dose.

If you take more Insomniger than you should

Contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining tablets with you. Symptoms of overdose include drowsiness, confusion and a general feeling of sluggishness (lethargy). In more serious cases of overdose, symptoms include uncontrollable movements, floppiness, shallow or slow breathing, dizziness, light-headedness or fainting on standing up or unconsciousness (including coma, which can, rarely, become fatal).

If you forget to take Insomniger

If you are still likely to have uninterrupted sleep of 7-8 hours, then take it as soon as you remember. Otherwise, if you miss a dose do not take a double dose to make up for a forgotten dose. Take your normal dose the following night.

If you stop taking Insomniger

You should only stop taking this medicine when your doctor tells you. Do not suddenly stop. If this happens you may suffer from side effects such as feeling nervous, depressed, irritable, suffer from sleep problems, sweating, being sick, confusion, psychosis, fits or shaking.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. In some patients, particularly the elderly, Insomniger can cause unusual reactions.

Contact a doctor immediately if you experience any of the following side effects:

Rare (may affect up to 1 in 1,000 people):

- unusual bruising or bleeding or an increase in the number of infections (such as sore throat) that you may get – this may be a sign of changes in the number of different types of blood cells as seen in blood tests

Not known (frequency cannot be estimated from the available data):

- serious sudden allergic reaction with symptoms that include feeling dizzy or faint, rash, itchy skin, swelling of the face, lips, tongue or throat that may cause difficulty breathing or swallowing
- attempting to harm or kill yourself, thoughts about harming or killing yourself

- serious, life-threatening, difficulty breathing

Other possible side effects:

Very common (may affect more than 1 in 10 people):

- tiredness or less alert during the next day

Common (may affect up to 1 in 10 people):

- depression or worsening of existing depression
- confusion
- dizziness
- drowsiness
- lack of co-ordination
- feeling weak, feeling tired

Uncommon (may affect up to 1 in 100 people):

- lack of sex drive, problems getting or keeping an erection, a change in the ability to obtain orgasm or in the quality of the sensation
- emotional disorder
- feeling sick (nausea)
- slow response to stimuli
- lack of attention

Rare (may affect up to 1 in 1,000 people):

- low blood pressure
- abnormal liver function levels as shown in blood tests

Not known (frequency cannot be estimated from the available data):

- overproduction of a hormone causing fluid retention with symptoms that include weakness, tiredness or confusion (syndrome of inappropriate antidiuretic hormone secretion (SIADH))
- low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits or coma
- restlessness
- agitation
- irritability
- aggressiveness
- delusions (beliefs which are not normally consistent with reality)
- rage
- nightmares
- hallucinations (feeling, hearing or seeing things which are not there)
- hostility
- sexual arousal problems
- anger
- sleeping problems (such as restless sleep, difficulty sleeping)
- drug dependence
- severe thought disturbances (psychoses)
- odd or unusual behaviour
- numbed emotions

- reduced ability to concentrate, memory loss
- headaches
- eyesight problems (such as double vision, blurred vision)
- muscle weakness
- dry mouth
- upset stomach pain, difficulty or delay emptying bowels
- coma
- unusual, uncontrollable, movements, including trembling and shaking of the hands and fingers, twisting movements of the body, shuffling walk and stiffness of the arms and legs
- convulsion, fit or seizure
- shaking
- a feeling of spinning or whirling when you are not actually moving (vertigo)
- difficulty speaking
- temporarily stopping breathing while awake or sleeping
- a lung condition with symptoms that include long-term breathing problems, shortness of breath, chronic cough (COPD)
- yellowing of the skin and the whites of the eyes (jaundice)
- increased enzyme levels as shown in blood tests
- hair loss (alopecia)
- abnormally low body temperature
- skin rashes
- anxiety

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Insomniger

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the bottle, container, blister or carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Bottles: Keep the container tightly closed and replace the cap immediately after use in order to protect from moisture.

Blisters: Store in the original package in order to protect from moisture.

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 to protect the environment.

6. Contents of the pack and other information

What Insomniger contains

Each tablet contains 10 mg or 20 mg of temazepam as the active substance. The other ingredients are lactose monohydrate, maize starch, gelatin, talc and magnesium stearate.

What Insomniger looks like and contents of the pack

Your medicine comes as a white to pale yellow round tablet in either two strengths of 10 mg or 20 mg. The tablets are marked 'T/10' for the 10 mg and 'T/20' for the 20 mg on one side and 'G' on the other.

Insomniger is available in amber glass bottles, plastic containers or blisters of 7, 10, 14, 28, 30, 56, 60, 84, 90, 100, 250 and 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. T/A Gerard Laboratories, Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturers

Generics (UK) Ltd. Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

McDermott Laboratories Ltd. T/A Gerard Laboratories, Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Mylan Hungary Kft, H-2900 Komarom, Mylan utca 1, Hungary.

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom	Temazepam 10 mg/20 mg tablets
Ireland	Insomniger 10 mg/20 mg tablets

This leaflet was last revised in Feb 2022.