

PACKAGE LEAFLET

Package leaflet: Information for the patient

Gerax 250 microgram Tablets
Gerax 500 microgram Tablets
Gerax 1 mg Tablets
alprazolam

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

1. What Gerax is and what it is used for

Gerax is a tranquilliser containing the active substance alprazolam. Alprazolam belongs to one of a group of medicines called benzodiazepines. Benzodiazepines affect chemical activity in the brain to promote sleep and to reduce anxiety and worry.

Gerax tablets are only used to treat severe anxiety and severe anxiety associated with depression. Gerax is not recommended for the treatment of depression.

Gerax tablets should only be used for short-term treatment of anxiety. The overall duration of treatment should not be more than 12 weeks including a period where the dose is gradually reduced (this is called dose 'tapering').

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Gerax

Do not take Gerax:

- if you are allergic to alprazolam or other similar benzodiazepine medicines, or to any of the other ingredients of this medicine (listed in section 6).
- if you suffer from a disease called 'myasthenia gravis' where you suffer from very weak and tired muscles.
- if you have severe chest problems or breathing difficulties (e.g. chronic bronchitis or emphysema).

- if you have severe liver problems.
- If you have ‘sleep apnoea’ – this is a condition where your breathing becomes irregular, even stopping for short periods, while you are asleep.

Warnings and precautions

Talk to your doctor or pharmacist before taking Gerax:

- if you are pregnant, think you might be pregnant now, are planning to become pregnant or if you are breast-feeding (see also the sections on ‘Pregnancy’ and ‘Breast-feeding’ for more information).
- if you have problems with your lungs, kidneys or liver.
- if you have ever felt so depressed that you have thought about taking your own life.
- if you have ever suffered from any mental illness that required hospital treatment
- if you have abused drugs or alcohol in the past or find it difficult to stop taking medicines, drinking or taking drugs. Your doctor may want to give you special help when you need to stop taking these tablets because there have been reports of overdose related deaths.
- There is a risk of developing drug addiction/dependency when using Gerax.
- if you have been prescribed medicines for severe anxiety before, because your body can quickly become used to this type of medicine so that it no longer helps you.
- Benzodiazepines and related products should be used with caution in elderly, due to the risk of sedation and / or musculoskeletal weakness that can promote falls, often with serious consequences in this population.

Children and adolescents

Do not give this medicine to children and adolescents below the age of 18 years because safety and efficacy have not been established.

Other medicines and Gerax

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially medicines listed below as the effect of Gerax or the other medicine may change when taken at the same time:

- any other medicine to treat anxiety or depression (e.g. nefazodone, fluvoxamine, fluoxetine,) or to help you sleep (e.g. nitrazepam, flurazepam)
- strong pain killers (e.g. opioids such as morphine, codeine, propoxyphene).
- Antipsychotic medicines used to treat mental illnesses like schizophrenia.
- medicines to treat epilepsy (e.g. carbamazepine, gabapentin)
- medicines to treat fungal infections (e.g. ketoconazole, itraconazole, posaconazole, voriconazole)
- antihistamines to relieve allergies (e.g. chlorphenamine, promethazine)
- medicines to treat heart conditions (e.g. diltiazem, digoxin)
- medicines to treat HIV/AIDS (e.g. ritonavir)
- oral contraceptives (‘the pill’)
- cimetidine (for treating stomach ulcers)
- antibiotics (e.g. erythromycin, troleandomycin, clarithromycin, telithromycin)

If you are going to have an operation where you will be given a general anaesthetic, tell your doctor or anaesthetist that you are taking Gerax.

Concomitant use of Gerax and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) 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 Gerax together with opioids

the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all opioid 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.

Gerax with food, drink and alcohol

It is important not to drink any alcohol while you are taking Gerax, as alcohol increases the effects of the medicine. Please refer to section 3.

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 breast-feed while taking Gerax, as the drug may pass into breast milk.

Driving and using machines

Gerax may make you feel sleepy or woozy and make you lose concentration so it is very important you do not drive or operate machinery until you know how the tablets affect you.

Gerax contains lactose

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

Gerax contains sodium benzoate

This medicine contains 0.10 mg sodium benzoate in each tablet.

Gerax contains sodium

This medicine contains less than 1 mmol (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take Gerax

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will tell you how many tablets to take and when to take them.

Do **not** take your tablets with alcohol.

Adults

The recommended starting dose is 500 micrograms to 1 mg, taken in divided doses two or three times daily. If clinically required your doctor may increase your medicine in small increments. Where the dose does need to be increased, it is usual to increase the night time dose first, before the daytime doses to make sure you are more alert during the day. If you get side effects the doctor may lower your dose.

Elderly

If you are an older patient or you have kidney or liver problems, your doctor will start you on a lower dose of 250 micrograms twice a day. This does may be slowly increased if needed and if you do not get any side effects.

Use in children and adolescents

Gerax is not recommended for children and adolescents under the age of 18 years.

Route and/or method of administration

For oral use.

Duration of treatment

Gerax tablets are only used for short-term treatment (not more than 12 weeks). You will not normally be given a prescription for more than 4 weeks. The lowest possible effective dose and duration should be used and the patient should be reassessed for the need for continued treatment frequently. A decreased effect of the drug may develop if used for more than a few weeks.

If you take more Gerax than you should

It is important that you do not take more tablets than you are told to. If you do accidentally take too many tablets you may experience drowsiness, confusion, feeling cold, slurred speech, drop in blood pressure and difficulty breathing. If you do accidentally take too many tablets seek medical attention straight away.

If you forgot to take Gerax

If you forget to take a dose, take it as soon as you remember unless it is almost time for your next dose.

Do not take a double dose to make up for a missed dose.

If you stop taking Gerax

Always see your doctor before you stop taking Xanax tablets as the dose needs to be reduced gradually. If you stop taking the tablets or reduce the dose suddenly you can get 'rebound' effects which might cause you to become temporarily more anxious or restless or have difficulty sleeping. Some people may also experience 'withdrawal' effects (see Section 4 – Dependence and withdrawal symptoms). These symptoms will go away as your body re-adjusts. If you are worried, your doctor can tell you more about this.

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.

Reasons for seeing your doctor immediately

If you get any of these symptoms see your doctor straight away as treatment will need to be discontinued. Your doctor will then advise how treatment will be stopped.

- Very occasionally treatment with Gerax can cause serious behavioural or psychiatric effects - for example agitation, restlessness, aggressiveness, irritability, violent anger, false beliefs, nightmares and hallucinations or other inappropriate behaviour.
- Sudden wheeziness, difficulty in swallowing or breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).

Reasons for seeing your doctor as soon as possible

Tell your doctor as soon as possible if you get the following symptoms as your dose or treatment might need to be changed:

- Memory loss (amnesia)
- Yellowing of the skin and whites of the eyes (jaundice)

Dependence and withdrawal symptoms

It is possible to become dependent on medicines like Xanax while you are taking them which increases the likelihood of getting withdrawal symptoms when you stop treatment.

Withdrawal symptoms are more common if you:

- stop treatment suddenly
- have been taking high doses
- have been taking this medicine for long time
- have a history of alcohol or drug abuse.

This can cause effects such as headaches, muscle pain, extreme anxiety, tension, restlessness, confusion, mood changes, difficulty sleeping and irritability.

In severe cases of withdrawal you can also get the following symptoms: nausea (feeling sick), vomiting, sweating, stomach cramps, muscle cramps, a feeling of unreality or detachment, being unusually sensitive to sound, light or physical contact, numbness and tingling of the feet and hands, hallucinations (seeing or hearing things which are not there while you are awake), tremor or epileptic fits. **Please tell your doctor if any withdrawal symptoms get worse or do not go away.**

Other side effects that may occur include:

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

- depression
- sleepiness and drowsiness
- jerky, uncoordinated movements
- difficulty remembering
- slurred speech
- dizziness, light-headedness
- headaches
- constipation
- dry mouth
- tiredness
- irritability

Common (may affect up to 1 in 10 people)

- loss of appetite
- confusion and disorientation
- changes in your sex drive (men and women)
- nervousness or feeling anxious or agitated
- insomnia (inability to sleep or disturbed sleep)
- problems with balance and unsteadiness (similar to feeling drunk) especially during the day
- loss of alertness or concentration
- inability to stay awake, feeling sluggish
- shakiness or trembling
- double or blurred vision
- feeling sick (nausea)
- skin reactions
- changes in your weight

Uncommon (may affect up to 1 in 100 people)

- feeling elated or over-excited, which causes unusual behaviour

- hallucination (seeing or hearing things that do not exist)
- feeling agitated or angry
- incontinence (uncontrolled passing of urine)
- cramping pain in the lower back and thighs, which may indicate menstrual disorder
- muscle spasms or weakness
- drug addiction
- drug withdrawal symptoms

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

- in women, irregular periods or production of too much prolactin (the hormone that stimulates milk production)
- feeling hostile or aggressive
- abnormal thoughts
- twisting or jerking movements
- being hyperactive
- stomach upsets
- problems with liver function (this shows up in blood tests), inflammation of the liver (hepatitis)
- nervous system imbalance. Symptoms may include: fast heart-beat and unstable blood pressure (feeling dizzy, light-headed or faint)
- serious allergic reaction which causes swelling of the face or throat
- swelling of the ankles, feet or fingers
- skin reaction caused by sensitivity to sunlight.
- difficulty urinating or bladder control problems
- increased pressure in the eyes, which can also affect your vision
- drug abuse

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 HPRC 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 Gerax

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 label after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the container in the outer carton.

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. Contents of the pack and other information

What Gerax contains

The active substance is alprazolam.

Each Gerax 250 microgram tablet contains 250 micrograms of alprazolam.

Each Gerax 500 microgram tablet contains 500 micrograms of alprazolam.

Each Gerax 1 mg tablet contains 1 mg of alprazolam.

The other ingredients are lactose monohydrate (see section 2 ‘Gerax contains lactose’), microcrystalline cellulose, maize starch, sodium benzoate (E211) (see section 2 ‘Gerax contains sodium benzoate’), docusate sodium, povidone, anhydrous colloidal silica, sodium starch glycolate (Type A), magnesium stearate.

The 500 mg tablets also contain the colours indigo carmine (E132) and erythrosine (E127).

The 1 mg tablets also contain the colour indigo carmine (E132).

What Gerax looks like and contents of the pack

Your medicine comes as a tablet.

Gerax 250 microgram tablets are oval biconvex white tablets marked “AL | 0.25” on one side and “G” on the reverse.

Gerax 500 microgram tablets are oval biconvex pink tablets marked “AL | 0.5” on one side and “G” on the reverse.

Gerax 1 mg tablets are oval biconvex light blue tablets marked “AL | 1.0” on one side and “G” on the reverse.

Gerax is available in plastic bottles or blister packs of 100 tablets.

Marketing Authorisation Holder

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Manufacturer

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