KALMA

contains the active ingredient alprazolam

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about KALMA.

It does not contain all of 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 KALMA against the benefits this medicine is expected to 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 KALMA is used for

The name of your medicine is KALMA. It contains the active ingredient alprazolam.

It is used to treat:

- anxiety.
- panic attacks.

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

Your doctor, however, may have prescribed KALMA for another reason.

KALMA is available only with a doctor's prescription.

How it works

KALMA belongs to a group of medicines called benzodiazepines. These medicines are thought to work by their action on brain chemicals.

In general, benzodiazepines such as alprazolam are 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 benzodiazepines may lead to dependence on the medicine.

If you take KALMA for too long, it may become habit-forming. Benzodiazepines may lead to physical or psychological dependence. If you have any concerns, you should discuss this with your doctor.

This medicine is not recommended as the first choice of treatment for depression and psychosis as it can increase the risk of suicide.

Before you take KALMA

When you must not take it

Do not take this medicine if:

- **You are allergic to alprazolam, benzodiazepines 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.

- **You have had any of the following:**

  - **severe and chronic lung disease**

  - **myasthenia gravis, a condition which causes severe muscle weakness.**

- **You are pregnant.**

  KALMA may affect your unborn baby if you take it during pregnancy.

  Your doctor will discuss the risks and benefits of taking this medicine during pregnancy.

- **You are breastfeeding.**

  KALMA passes into the breast milk and may cause drowsiness, weight loss and feeding difficulties in the infant.

Do not give this medicine to a child unless advised by the child's doctor.

The safety and effectiveness of KALMA in children have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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 have, any medical conditions, especially the following:

- depression, psychosis or schizophrenia.
- borderline personality disorder (BPD)

- post-traumatic stress disorder (PTSD)
- epilepsy (fits or convulsions)
- liver, kidney or lung problems
- glaucoma (increased eye pressure)
- hypotension (low blood pressure)

Tell your doctor if you are pregnant or planning to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you have a history of alcohol or drug abuse, or find it difficult to stop taking medicines, drugs or drinking alcohol.

Your doctor may want to give you extra support when you need to stop taking this medicine.

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 KALMA.

Taking other medicines

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

Some medicines may be affected by KALMA or may affect how well KALMA works. You should be advised by your healthcare professional that your tolerance for alcohol and other Central Nervous System (CNS) depressants will be reduced. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

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

- other sleeping tablets, sedatives (medicines used to produce calmness) or tranquillisers
- muscle relaxants
- medicines for depression
- lithium, a medicine used to treat mood swings and some types of depression
- medicines used to treat epilepsy (fits and seizures) such as barbiturates
- some medicines used to treat high blood pressure
- antihistamines, medicines for allergies, hay fever or colds, some pain relievers, especially strong pain relievers such as codeine, morphine or propoxyphene
- disulfiram, a medicine used in the treatment of alcohol dependence

- cimetidine, a medicine commonly used to treat reflux and ulcers.
- some antibiotics such as erythromycin or clarithromycin
- oral contraceptives (birth control pill)
- HIV protease inhibitors, medicines used to treat HIV infection
- some antifungals, medicines used to treat fungal infections, such as ketoconazole or itraconazole

KALMA may produce additive depressant effects when using together with other medications, e.g. alcohol, sedatives, antidepressants, antipsychotics drugs, epilepsy drugs, hypnotics, relaxants, antihistamines, severe pain relievers and anaesthetics. This has the potential to significantly increase the effects on KALMA and may lead to addiction or result in death from overdose.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take KALMA

How much to take

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

They may differ from the information contained in this leaflet.

The dose varies from patient to patient.

Your doctor will tell you how much to take. Take KALMA exactly as directed by your doctor. Your doctor will decide the right dose for you.

Elderly patients and people with liver or kidney problems may need smaller doses.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How to take it

Swallow the tablets with a full glass of water.

KALMA 0.25 mg, 0.5 mg and 1 mg tablets can be divided in half along the scoreline if your doctor has prescribed half a tablet. KALMA 2 tablets can also be quartered.

When to take it

Take your tablet at about the same time each day.

Your doctor will tell you how many times a day you should take your medicine but taking it at the same time each day will have the best effect. It will also help you remember to take it.

KALMA can be taken with or without food.

However, taking the tablets immediately after food may reduce the sleepiness or drowsiness you may experience with this medicine.

How long to take it

Do not take KALMA for longer than your doctor has directed.

In general, benzodiazepines such as alprazolam are 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 benzodiazepines may lead to dependence on the medicine.

Continue taking your medicine for as long as your doctor tells you to and always see your doctor before you stop taking it.

Your dose will need to be reduced gradually to prevent unwanted side effects.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

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

If you have any questions about this, check with your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much KALMA.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Tell the doctor, nurse or pharmacist about any alcohol or other medicines which you have taken.

If you take too much KALMA, you may feel drowsy, tired, confused, dizzy; have a fast heartbeat, difficulty breathing; feel weak or become unconscious.

While you are taking KALMA

Things you must do

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

Tell all the doctors, dentists and pharmacists who are treating you that you are taking this medicine if:

- you become pregnant while taking this medicine.
- you plan to have surgery, including dental surgery.
- you are about to have any blood tests.
- you have to have any clinical tests such as an EEG (electroencephalogram).

Alprazolam may affect the results of some tests.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or ending your life. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

All thoughts of suicide must be taken seriously. Tell your doctor or a mental health professional immediately if you have any suicidal thoughts or other mental/mood changes.

If you feel this medicine is not helping your condition, tell your doctor.

Visit your doctor regularly so they can check on your progress and determine whether you need to keep taking this medicine.

Always discuss with your doctor any problems or difficulties during or after taking KALMA. If you are being treated for anxiety, be sure to tell your doctor how you feel, especially if your anxiety attacks are getting worse or more frequent.

This will help your doctor determine the best treatment for you.

Do not run out of your medicine.

It is important that you take your medicine as prescribed.

Things you must not do

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

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

Do not drive or operate machinery until you know how KALMA affects you.

This medicine may cause drowsiness, dizziness or light headedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Even if you take this medicine at night, you may still be drowsy or dizzy the next day.

Do not take KALMA for longer than your doctor has prescribed.

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

Do not increase your dose, without first checking with your doctor.

If your symptoms have returned even though you are taking the same dose, you should speak to your doctor, who will determine whether a dose adjustment is required.

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

If you have taken KALMA for a long period of time and suddenly stop taking it, you may experience withdrawal symptoms. Withdrawal symptoms may last for weeks or months and symptoms may include: extreme anxiety, shaking

(tremor) including involuntary movements, difficulty sleeping (insomnia), depression, problems with your perception, confusion, fits (convulsions), muscle cramps, headaches, tension, restlessness, irritability, stomach problems, being sick (vomiting) and sweating. More severe withdrawal symptoms include: a feeling of loss of identity/feeling detached from yourself (depersonalisation or derealisation), sensitivity to light, noise (including tinnitus) and physical contact, numbness or tingling in the hands or feet (paraesthesia), seeing or hearing things that are not real (hallucinations). KALMA should be stopped gradually to minimise occurrence of withdrawal symptoms.

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

Stopping this medicine suddenly may make your epilepsy worse.

Things to be careful of

Be careful when drinking alcohol while taking this medicine.

Your doctor may suggest you avoid alcohol or reduce the amount of alcohol you drink. Combining KALMA and alcohol can make you more sleepy, dizzy or lightheaded. Also, your tolerance to alcohol may be lower than usual.

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 KALMA.

This medicine helps most people with anxiety or panic attacks, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of taking this medicine, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

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

Do not be alarmed by the 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 or pharmacist if you notice any of the following and they worry you:

- drowsiness, tiredness
- dizziness, lightheadedness, confusion
- unsteadiness, clumsiness
- slurred speech
- blurred vision
- headache
- loss of appetite
- nausea (feeling sick)
- constipation
- dry mouth
- stomach upsets
- changes in sex drive
- urinary problems
- menstrual irregularities.

The above list includes the more common side effects. They are usually mild and do not last very long.

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

- loss of alertness or concentration, memory loss

- abnormal thinking
- nervousness or feeling anxious
- shakiness or tremor, muscle weakness
- involuntary movements
- swelling of hands, ankles or feet
- yellowing of the skin and whites of the eyes.

The above list serious side effects that may require medical attention. Serious side effects are not common.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- aggressive behaviour, hostility, agitation, violent anger, hallucinations
- allergic reactions such as swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; skin rash, hives or itching.

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

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

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

After taking KALMA

Storage

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

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place, protected from light, where the temperature stays below 25°C.

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

Do not leave your medicine in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your medicine 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.

Disposal

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

Product description

What it looks like

KALMA 0.25 tablets are white, oval, scored tablets, marked AL|0.25 and G

Available in bottles of 10 and 50 tablets.

KALMA 0.5 tablets are pale pink, oval, scored tablets, marked AL|0.5 and G.

Available in bottles of 10 and 50 tablets.

KALMA 1 tablets are pale blue, oval, scored tablets, marked AL|1.0 and G

Available in bottles of 10 and 50 tablets.

KALMA 2 tablets are approximately 9.5 mm x 9.0 mm, white, oval, bevel edged, quadrisect tablet marked "A" in the upper left quadrant, "L" in the upper right quadrant, "G" in the lower left quadrant and "2" in the lower right quadrant on one side, and plain quadrisect on the other side.

Available in bottles of 50 tablets.

Ingredients

The active ingredient in KALMA is alprazolam.

Each tablet contains 0.25 mg, 0.5 mg, 1 mg or 2 mg of alprazolam.

The tablets also contain the following inactive ingredients:

- lactose monohydrate
- sodium benzoate
- maize starch
- magnesium stearate
- sodium starch glycollate
- microcrystalline cellulose
- colloidal anhydrous silica
- povidone
- docusate sodium
- indigo carmine aluminium lake

  (KALMA 0.5 mg and KALMA 1 mg only)
- erythrosine aluminium lake

  (KALMA 0.5 mg only).

KALMA also contains sugars (as lactose), benzoates and sulfites.

The tablets are gluten free.

Sponsor

Alphapharm Pty Ltd

Level 1, 30 The Bond

30 - 34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian Registration Numbers

KALMA 0.25 bottle - AUST R 46835

KALMA 0.5 bottle - AUST R 46837

KALMA 1 bottle - AUST R 46839

KALMA 2 bottle - AUST R 63993

KALMA 0.25 blister - AUST R 385850

KALMA 0.5 blister - AUST R 385851

KALMA 1 blister - AUST R 385852

KALMA 2 blister AUST R 385853

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