

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 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 Kalma is used for

Kalma is used for the short-term treatment of anxiety. Anxiety or tension associated with the normal stress of everyday life usually does not require treatment with medicines.

Kalma is also used to treat 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 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 Kalma 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.

Kalma is not recommended for use in children, as its safety and effectiveness in children have not been established.

Kalma is available only with a doctor's prescription.

Before you take Kalma

When you must not take it

Do not take Kalma if you are allergic to:

- * medicines containing alprazolam
- * any other benzodiazepine medicine
- * 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 Kalma if you have:

- * severe and chronic lung disease
- * myasthenia gravis, a condition where there is severe muscle weakness.

Do not take Kalma if the expiry date (Exp.) printed on the pack has passed.

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

Do not take Kalma if you are breastfeeding.

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

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

Do not take Kalma 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.

Your baby may absorb this medicine in the womb and develop muscle weakness or breathing problems. Your doctor will discuss the risks and benefits of taking Kalma during pregnancy.

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

- * hypotension (low blood pressure)
- * myasthenia gravis (severe muscle weakness)
- * liver or kidney problems

- * lung problems
- * a blood disorder - low red blood cell, white blood cell or platelet count
- * glaucoma (increased eye pressure)
- * depression, psychosis or 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 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 without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Kalma may interfere with each other. These include:

- * other sleeping tablets, sedatives or tranquillisers
- * muscle relaxants
- * medicines for depression
- * lithium, a medicine used to treat mood swings and some types of depression
- * medicines used to treat certain mental and emotional conditions
- * medicines used to treat epilepsy such as barbiturates
- * antihistamines, medicines for allergies, hay fever or colds
- * some pain relievers such as codeine and morphine
- * anaesthetics
- * anticholinergics, medicines for travel sickness, stomach cramps or Parkinson's Disease
- * disulfiram, medicine used in the treatment of alcohol dependence
- * cimetidine, a medicine commonly used to treat reflux and ulcers.

- * some antibiotics such as erythromycin
- * oral contraceptives (birth control pill)
- * HIV protease inhibitors, medicines used to treat HIV infection.

These medicines may be affected by Kalma or may affect how it works. You may need different amounts of your medicine, or you may need to take different medicines.

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

How to take Kalma

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 bottle, ask your doctor or pharmacist for help.

How much to take

The dose varies from patient to patient.

Take Kalma exactly as directed by your doctor.

Your doctor will tell you how much to take.

The usual starting dose ranges from 0.5 mg to 1.5 mg a day. Your doctor may gradually increase your dose, depending on how severe your symptoms are, how you respond to this medicine and whether you are taking other medicines.

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

How to take it

Swallow the tablets with a 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

Kalma is usually taken as divided doses throughout the day.

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 Kalma.

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.

How long to take it for

Do not take Kalma for longer than your doctor says.

In general, benzodiazepines such as Kalma 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.

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.

If you take too much Kalma, you may feel drowsy, tired, confused, dizzy, have 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 Kalma.

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

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking Kalma.

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

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.

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

If you have to have any clinical tests such as an EEG (electroencephalogram), tell your doctor that you are taking Kalma.

Kalma may affect the results of some tests.

Things you must not do

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

This medicine may cause drowsiness, dizziness or lightheadedness 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 Kalma at night, you may still be drowsy or dizzy the next day.

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

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

Stopping Kalma suddenly may make your condition worse and cause other unwanted effects such as trouble sleeping, irritability and nervousness. Your doctor may want you to gradually reduce the amount of Kalma you are taking before stopping completely.

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

Stopping this medicine suddenly may make your epilepsy worse.

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

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

Things to be careful of

Be careful when drinking alcohol while taking Kalma.

Your doctor may suggest you avoid alcohol or reduce the amount of alcohol you drink while you are taking Kalma. 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.

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:

- * drowsiness, tiredness
- * dizziness, lightheadedness, confusion
- * fatigue
- * unsteadiness, clumsiness
- * anxiety, irritability and sleep problems
- * concentration difficulties
- * tremor
- * depression
- * slurred speech
- * blurred vision
- * headache
- * loss of appetite
- * increase or decrease in weight
- * stomach upsets
- * irregular menstrual periods

- * incontinence
- * changes in sex drive.

The above list includes the more common or mild side effects of Kalma. They are usually short-lived.

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

- * an unusual feeling of anger, excitement or overactivity
- * manic behaviour or hypomania (feeling melancholy/depressed)
- * yellowing of the eyes or skin (jaundice)
- * muscle weakness
- * memory loss
- * 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 if you notice anything that is making you feel unwell.

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

After taking Kalma

Storage

Keep Kalma 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 bottle until it is time to take them.

Keep your tablets in a cool dry place where the temperature stays below 30 degrees C.

Do not store Kalma or any other medicine in the bathroom or near a

sink. Do not leave Kalma in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Kalma, 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 comes in 4 strengths:

- * Kalma 0.25 - white, oval, scored tablet, marked AL|0.25 and G
- * Kalma 0.5 - pale pink, oval, scored tablet, marked AL|0.5 and G
- * Kalma 1 - pale blue, oval, scored tablet, marked AL|1.0 and G
- * Kalma 2 - white, oblong, triple scored tablet, marked |A|L| and |G|2|.

Each pack contains 50 tablets.

Ingredients

The active ingredient in Kalma is alprazolam. Each Kalma tablet contains 0.25 mg, 0.5 mg, 1 mg or 2 mg of alprazolam.

The tablets also contain the following inactive ingredients:

- * lactose
- * sodium benzoate (211)
- * maize starch
- * magnesium stearate
- * sodium starch glycollate
- * microcrystalline cellulose
- * colloidal anhydrous silica
- * povidone
- * docusate sodium
- * indigo carmine CI 73015 (132) (Kalma 0.5 mg and Kalma 1 mg only)

- * erythrosine CI 45430 (127) (Kalma 0.5 mg only).

The tablets are gluten free.

Manufacturer

Kalma is made in Australia by:
Alphapharm Pty Limited
(ABN 93 002 359 739)
Chase Building 2
Wentworth Park Road
Glebe NSW 2037

Phone: (02) 9298 3999

Medical Information

Phone: 1800 028 365

Australian registration numbers:

Kalma 0.25 - AUST R 46835

Kalma 0.5 - AUST R 46837

Kalma 1 - AUST R 46839

Kalma 2 - AUST R 63993

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