

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

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### 1. Why am I taking KALMA?

KALMA contains the active ingredient alprazolam. KALMA is used to treat anxiety and panic attacks. For more information, see Section [1. Why am I taking KALMA?](#) in the full CMI.

### 2. What should I know before I take KALMA?

Do not take if you have ever had an allergic reaction to alprazolam or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I take KALMA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with KALMA and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take KALMA?

Take KALMA exactly as directed by your doctor. Your doctor will decide the right dose for you. More instructions can be found in Section [4. How do I take KALMA?](#) in the full CMI.

### 5. What should I know while taking KALMA?

#### Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking KALMA.
- Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.
- Call your doctor or a mental health professional straight away if you have any suicidal thoughts or

	<p>other mental/mood changes.</p>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not take KALMA for longer than your doctor has prescribed.</li> <li>● Do not stop taking KALMA, or change the dose, without checking with your doctor.</li> <li>● Do not suddenly stop taking KALMA if you suffer from epilepsy.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● Do not drive or operate machinery until you know how KALMA affects you.</li> <li>● KALMA 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.</li> </ul>
<p><b>Drinking alcohol</b></p>	<ul style="list-style-type: none"> <li>● Be careful when drinking alcohol while taking this medicine.</li> <li>● Combining KALMA and alcohol can make you more sleepy, dizzy or</li> </ul>

	lightheaded. Also, your tolerance to alcohol may be lower than usual.
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep your tablets in a cool dry place, protected from light, where the temperature stays below 25°C.</li> <li>• Keep your tablets in the pack until it is time to take them.</li> </ul>

For more information, see Section [5. What should I know while taking KALMA?](#) in the full CMI.

## 6. Are there any side effects?

**Less serious side effects:** drowsiness, tiredness, dizziness, lightheadedness, confusion, unsteadiness, slurred speech, blurred vision, headache, loss of appetite, nausea (feeling sick), constipation, dry mouth, stomach upsets, urinary problems.

**Serious side effects:** loss of alertness or concentration, memory loss, abnormal thinking, nervousness, feeling anxious, shakiness or tremor, involuntary movements, swelling of hands, ankles or feet, yellowing of the skin and whites of the eyes, 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. **This is not a complete list of side effects.** For more information, including what to do if you

have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# KALMA®

**Active ingredient:** *alprazolam*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about taking KALMA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking KALMA.**

**Where to find information in this leaflet:**

- [1. Why am I taking KALMA?](#)
- [2. What should I know before I take KALMA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take KALMA?](#)
- [5. What should I know while taking KALMA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking KALMA?

**KALMA contains the active ingredient alprazolam.** KALMA belongs to a group of medicines called benzodiazepines. These medicines are thought to work by their action on brain chemicals.

**KALMA is used to treat:**

- **anxiety**

- **panic attacks**

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.**

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

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

## **2. What should I know before I take KALMA?**

### **Warnings**

#### **Do not take KALMA 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

Always check the ingredients to make sure you can take this medicine.

- you have had any of the following:
  - severe and chronic lung disease
  - myasthenia gravis, a condition which causes severe muscle weakness
- the expiry date printed on the pack has passed 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.

### **Check with your doctor if you:**

- are allergic to any other medicines, foods, dyes or preservatives
- 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).
- 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.

- plan to have surgery.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

**Do not take KALMA if you are pregnant.**

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

**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.

**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.

## **Use in children**

**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.

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

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your 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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect KALMA.**

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

## **4. How do I take KALMA?**

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

They may differ from the information contained in this leaflet.

### **How much to take**

- Take KALMA exactly as directed by your doctor. Your doctor will decide the right dose for you.
- The dose varies from patient to patient.
- Elderly patients and people with liver or kidney problems may need smaller doses.

### **When to take KALMA**

- 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 KALMA.

### **How to take KALMA**

- 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.

## **How long to take KALMA for**

- **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 KALMA**

KALMA should be taken regularly at the same time each day.

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 or you have any questions about this, ask 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 KALMA**

If you think that you or anyone else has taken too much KALMA, urgent medical attention may be needed.

### **You should immediately:**

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

**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.

## 5. What should I know while taking KALMA?

### Things you should 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 KALMA
  - 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 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.

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

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.

## **Things you should not do**

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

KALMA 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 KALMA, 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.

## **Driving or using machines**

**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.

## **Drinking alcohol**

**Be careful when drinking alcohol while taking KALMA.**

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.

## **Things to be careful of**

**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.

## **Looking after your medicine**

- Store below 25°C.

- Keep your tablets in the pack until it is time to take them. If you take your tablets out of the pack they may not keep well.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

**Keep it where young children cannot reach it.**

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

## **Getting rid of any unwanted medicine**

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by the list of possible side effects. You may not experience any of them.

### **Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>● drowsiness, tiredness</li><li>● dizziness, lightheadedness, confusion</li><li>● unsteadiness, clumsiness</li><li>● slurred speech</li><li>● blurred vision</li><li>● headache</li><li>● loss of appetite</li><li>● nausea (feeling sick)</li><li>● constipation</li><li>● dry mouth</li><li>● stomach upsets</li><li>● changes in sex drive</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p>This list includes the more common side effects. They are usually mild and do not last very long.</p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• urinary problems</li> <li>• menstrual irregularities</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• loss of alertness or concentration, memory loss</li> <li>• abnormal thinking</li> <li>• nervousness or feeling anxious</li> <li>• shakiness or tremor, muscle weakness</li> <li>• involuntary movements</li> <li>• swelling of hands, ankles or feet</li> <li>• yellowing of the skin and whites of the eyes</li> </ul>	<p><b>Tell your doctor or seek medical advice as soon as possible if you notice any of these serious side effects.</b></p> <p>These serious side effects are not common.</p>
<ul style="list-style-type: none"> <li>• aggressive behaviour, hostility, agitation, violent anger, hallucinations</li> <li>• allergic reactions such as swelling of the face, lips or tongue which may cause difficulty in</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
swallowing or breathing; skin rash, hives or itching	These serious side effects are rare.

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

### **What KALMA contains**

<b>Active ingredient</b>	alprazolam
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<b>(main ingredient)</b>	
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>● lactose monohydrate</li> <li>● sodium benzoate</li> <li>● maize starch</li> <li>● magnesium stearate</li> <li>● sodium starch glycollate</li> <li>● microcrystalline cellulose</li> <li>● colloidal anhydrous silica</li> <li>● povidone</li> <li>● docusate sodium</li> <li>● indigo carmine aluminium lake (KALMA 0.5 mg and KALMA 1 mg only)</li> <li>● erythrosine aluminium lake (KALMA 0.5 mg only).</li> </ul>
<b>Potential allergens</b>	benzoates, sugars as lactose and trace quantities of sulfites

**Do not take this medicine if you are allergic to any of these ingredients.**

## What KALMA looks like

KALMA 0.25 mg tablet is 9mm x 5.5mm oval, white tablet debossed AL|0.25 on one side, G on the reverse.

(Blister: AUST R 385850).

KALMA 0.5 mg tablet is 9mm x 5.5mm oval, pale pink tablet, debossed AL|0.5 on one side, G on the reverse.

(Blister: AUST R 385851).

KALMA 1 mg tablet is 9mm x 5.5mm oval, pale blue tablet, debossed AL|1.0 on one side, G on the reverse.

(Blister: AUST R 385852).

KALMA 2 mg tablet is 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, "2" in the lower right quadrant on one side, plain quadrisect on the other side.

(Blister: AUST R 385853).

## Who distributes KALMA

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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