

# GenRx Alprazolam

contains the active ingredient, alprazolam (al-PRAZ-oh-lam)

## Consumer Medicine Information

For a copy of a large print leaflet Ph: 1800 195 055

### What is in this leaflet

#### Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about alprazolam. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

**The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.**

#### Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from [www.apotex.com.au](http://www.apotex.com.au).

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits he/she expects it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

**Keep this leaflet with your medicine. You may want to read it again.**

### What this medicine is used for

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

It is used to treat:

- anxiety
- panic attacks.

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

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

#### How it works

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

In general, benzodiazepines such as alprazolam should be 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.

#### Use in children

This medicine should not be used in children.

### Before you take this medicine

#### When you must not take it

#### Do not take this medicine if:

- **You have or have had any of the following:**
  - severe muscle weakness known as myasthenia gravis
  - severe and chronic lung disease.
- **You are intolerant to lactose - these tablets contain lactose.**
- **You are hypersensitive to, or have had an allergic reaction to, alprazolam, benzodiazepines or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

**If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**

- The expiry date (EXP) printed on the pack has passed.

- The packaging is torn, shows signs of tampering or it does not look quite right.

### *Before you start to take it*

#### **Before you start taking this medicine, tell your doctor if:**

1. You have allergies to:
  - any other medicines
  - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
  - depression, psychosis or schizophrenia
  - fits or convulsions
  - liver, kidney or lung disease
  - glaucoma (high pressure in the eye)
  - low blood pressure.
3. You have a history of alcohol or drug abuse, or find it difficult to stop taking medicines, drugs or drinking alcohol.
4. You have a history of behavioural or mental conditions, with or without current medical treatment. These may increase your chance of behavioural side effects.
5. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
6. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
7. You are planning to have surgery or an anaesthetic.
8. You are currently receiving or are planning to receive dental treatment.
9. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

### *Taking other medicines*

Some medicines may interact with alprazolam. These include:

- sedatives (medicines used to produce calmness) or tranquilisers
- sleeping tablets
- medicines for depression
- medicines used to treat certain mental and emotional conditions, such as antipsychotics
- medicines for allergies, such as hay fever, e.g. antihistamines or cold tablets
- pain relievers especially strong pain relievers, e.g. containing codeine or opioids (codeine-like medicines)
- muscle relaxants
- medicines to control fits or seizures
- cimetidine (a medicine used to treat reflux and ulcers)
- disulfiram (a medicine used in the treatment of alcoholism)
- antibiotics, such as erythromycin
- antifungals, such as ketoconazole and itraconazole
- oral contraceptives (birth control pill)
- HIV protease inhibitors, medicines used to treat HIV infection
- lithium (a medicine used to treat mood swings and some types of depression)
- medicines used to treat high blood pressure
- digoxin (a medicine used to control heart beats).

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with alprazolam.

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### **How to take this medicine**

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Follow carefully all directions given to you by your doctor. Their

instructions may be different to the information in this leaflet.

### *How much to take*

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

### *How to take it*

Swallow the tablets with a full glass of water.

### *When to take it*

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

Alprazolam can be taken immediately after meals or on an empty stomach. However, side effects such as sleepiness or drowsiness may be reduced if you take your medicine immediately after meals.

### *How long to take it*

Continue taking your medicine for as long as your doctor tells you.

#### **Do not take alprazolam for longer than your doctor tells you.**

Usually your medicine should be used for short periods only (for example, 2-4 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 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 it as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you experiencing side effects.

If you are unsure about whether to take your next dose, ask your doctor or pharmacist.

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

*If you take too much (overdose)*

**If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.**

**Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

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## While you are taking this medicine

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### *Things you must do*

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

**Always discuss with your doctor any problems or difficulties during or after taking your medicine.**

**If you are being treated for anxiety, be sure to discuss with your doctor any problems you may have and how you feel, especially if your anxiety attacks are getting worse or more frequent.**

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

**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.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

### *Things you must not do*

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor

**Do not suddenly stop taking your medicine if you suffer from epilepsy.**

Stopping your medicine suddenly may make your epilepsy worse. Do not take your medicine to treat any other complaints unless your doctor tells you to.

### *Things to be careful of*

**Be careful when driving or operating machinery until you know how this medicine affects you.**

This medicine may cause drowsiness or dizziness in some people and therefore may affect alertness.

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

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

Taking your medicine with alcohol can make you more sleepy, dizzy or lightheaded. Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you

drink while you are taking your medicine.

**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.

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## Possible side effects

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Tell your doctor as soon as possible if you do not feel well while you are taking alprazolam or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

**Tell your doctor if you notice any of the following:**

- drowsiness, tiredness, excessive sleepiness
- dizziness, lightheadedness
- clumsiness, unsteadiness
- disoriented
- slurred speech
- lack of appetite
- nausea (feeling sick)
- constipation
- dry mouth
- change in sex drive
- headache
- blurred vision
- insomnia
- weight changes.

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

These may be serious side effects and you may need medical attention:

- loss of alertness or concentration, memory loss
- nervousness or feeling anxious
- shakiness or tremor, muscle weakness or spasms
- swellings of hands, ankles or feet
- depression

- hypomania, with symptoms such as heightened energy ("wired"), lowered inhibitions and euphoria.

**If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

These are very serious side effects and you may need urgent medical attention or hospitalisation. These side effects are usually very rare:

- aggressive behaviour, hostility, agitation, violent anger, hallucinations
- yellowing of the skin and whites of the eyes.

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

### *Allergic reactions*

**If you think you are having an allergic reaction to alprazolam, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

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## Storage and disposal

### *Storage*

Keep your medicine in their original packaging until it is time to take them.

If you take the tablets out of their original packaging they may not keep well.

**Keep your medicine in a cool dry place where the temperature is below 25°C.**

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Do not leave your medicine on a window sill or in the car on hot days.

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 medicine has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.**

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## Product description

### *What the tablets look like*

The 1 mg tablets are blue, oval biconvex tablets, scored and engraved "APO" over "1" on one side, other side plain.

They are available in blister packs of 50 tablets and in bottles of 50 tablets.

The 2 mg tablets are white, rectangular flat-faced on one side tablets, engraved "APO 2" with centre partial bisect and two bisects on upper side, deep centre bisect with sloped faces toward two bisects on lower side.

They are available in bottles of 50 tablets.

### *Ingredients*

The active ingredient is alprazolam.

Each tablet contains 1 mg or 2 mg of alprazolam.

The tablets also contain the following inactive ingredients:

- cellulose - microcrystalline
- lactose
- croscarmellose sodium
- magnesium stearate

- indigo carmine CI 73015 (only contained in the 1 mg tablets).

The tablets are gluten-free, sucrose-free, tartrazine-free and free of any other azo dyes.

### *Australian Registration Numbers*

GenRx Alprazolam 1 mg tablets - blisters - AUST R 79802.

GenRx Alprazolam 1 mg tablets - bottles - AUST R 80935 (not marketed).

GenRx Alprazolam 2 mg tablets - bottles - AUST R 80934.

### *Sponsor*

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