

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about ALPRAX.

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 ALPRAX 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 ALPRAX is used for

ALPRAX is used to treat

- anxiety
- panic attacks.

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

ALPRAX 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 ALPRAX 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.

ALPRAX is not recommended for use in children, as there have been no studies of its effects in children.

ALPRAX is available only with a doctor's prescription.

Before you take ALPRAX

When you must not take it

Do not take ALPRAX if you are allergic to:

- medicines containing alprazolam
- any other benzodiazepine medicine
- any of the ingredients listed at the end of this leaflet.

Do not take ALPRAX if you have:

- severe and chronic lung disease
- severe muscle weakness known as myasthenia gravis.

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

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

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 doctor will discuss the risks and benefits of taking ALPRAX during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

ALPRAX may pass into the breast milk and cause drowsiness and feeding difficulties in the baby. Your doctor will discuss the risks and benefits of taking ALPRAX when breastfeeding.

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

- depression, psychosis or schizophrenia
- glaucoma (high pressure in the eye)
- epilepsy (fits or convulsions)
- liver, kidney or lung disease
- high or low blood pressure
- previous problems with addiction to medicine.

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

Tell your doctor if you drink alcohol regularly.

Alcohol may increase the effects of ALPRAX.

Taking other medicines

Tell your doctor 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 may be affected by ALPRAX, or may affect how well it works. These include:

- sleeping tablets, sedatives or tranquillisers
- medicines for depression
- lithium, a medicine used to treat mood swings and some types of depression
- antipsychotics, medicines used to treat certain mental and emotional conditions
- medicines to control epilepsy and fits
- antihistamines, medicines used to prevent or relieve the symptoms of allergy (such as hayfever)
- muscle relaxants
- some pain relievers
- cimetidine, a medicine commonly used to treat reflux and ulcers
- disulfiram, a medicine used in alcohol abuse
- oral contraceptives

- some macrolide antibiotics, e.g. erythromycin
- medicines to treat HIV infection (ritonavir).

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take ALPRAX

How much to take

The dose varies from patient to patient.

Your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your condition and whether or not you are taking any other medicines.

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

How to take ALPRAX

Swallow the tablets with a glass of water.

ALPRAX can be taken with or without food.

If you forget to take ALPRAX

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.

How long to take ALPRAX for

Keep taking ALPRAX for as long as your doctor recommends.

In general, benzodiazepines such as ALPRAX should be taken for short periods only (such as 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 take too much ALPRAX (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much ALPRAX. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much ALPRAX, you may feel drowsy, tired, confused, dizzy, have difficulty breathing, feel weak or become unconscious.

While you are taking ALPRAX

Things you must do

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

Tell all the doctors, dentists and pharmacists who are treating you that you are taking ALPRAX.

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

Visit your doctor regularly so they can check on your progress.

Your doctor will check your condition to see whether you should continue to take ALPRAX.

Tell your doctor if you feel that ALPRAX is not helping your condition.

Things you must not do

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

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

Do not take ALPRAX for a longer period than your doctor has prescribed.

Do not stop taking ALPRAX, or lower the dose, without first checking with your doctor.

Your doctor may want you to gradually reduce the amount of ALPRAX you are taking before stopping completely. This may help reduce the possibility of unwanted side effects.

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

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

Things to be careful of

Be careful when drinking alcohol while taking ALPRAX. Combining ALPRAX and alcohol can make you more sleepy, dizzy or lightheaded.

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

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 ALPRAX.

Like all other medicines, ALPRAX may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the 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
- memory problems
- unsteadiness, clumsiness
- slurred speech
- blurred vision
- tremor
- changes in weight
- impaired sexual function
- anxiety, irritability and sleep problems after you stop taking ALPRAX.

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

- unusual feelings of anger, excitement or overactivity
- yellowing of the eyes or skin (jaundice).

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using ALPRAX

Storage

Keep ALPRAX 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 blister pack of tablets in a cool dry place where the temperature stays below 25°C.

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

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

Do not leave ALPRAX in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ALPRAX, 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

ALPRAX comes in 4 strengths of tablets:

- ALPRAX 0.25 - oval white tablet A | 25 and >
- ALPRAX 0.5 – oval pink tablet marked A | 5 and >
- ALPRAX 1 – oval light blue tablet marked A | 1 and >
- ALPRAX 2 – rectangular white tablet marked | A | 2 | and triple scored.

Each pack contains 50 tablets.

Ingredients

The active ingredient in ALPRAX is alprazolam:

- each ALPRAX 0.25 tablet contains 0.25 mg of alprazolam
- each ALPRAX 0.5 tablet contains 0.5 mg of alprazolam
- each ALPRAX 1 tablet contains 1 mg of alprazolam
- each ALPRAX 2 tablet contains 2 mg of alprazolam.

The tablets also contain:

- lactose
- microcrystalline cellulose
- maize starch
- sodium benzoate
- docusate sodium
- povidone
- colloidal anhydrous silica
- sodium starch glycollate
- magnesium stearate
- Pigment Blend Purple PB20026 (ALPRAX 0.5 only)
- Indigo Carmine CI 73015 (132) (ALPRAX 1 only).

The tablets are gluten free.

Manufacturer

Sigma Pharmaceuticals (Australia) Pty Ltd
96 Merrindale Drive
Croydon Vic 3136
Tel: 03 - 9839 2800

Australian registration numbers:
ALPRAX 0.25 - Aust R 82638
ALPRAX 0.5 - Aust R 82640
ALPRAX 1 - Aust R 82643
ALPRAX 2 – Aust R 82644

Date of preparation: July 2009.