

Alprazolam Sandoz®

alprazolam tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Alprazolam Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT ALPRAZOLAM SANDOZ IS USED FOR

This medicine is used to treat:

- anxiety
- panic attacks.

It contains the active ingredient alprazolam.

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

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

Your doctor may have prescribed it for another reason.

This medicine may be addictive.

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

There is not enough information to recommend the use of this medicine for children.

BEFORE YOU TAKE ALPRAZOLAM SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- alprazolam, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.
- any other benzodiazepine medicine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you have any of the following medical conditions:

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

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 have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

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

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

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

Tell your doctor if you drink alcohol regularly.

Alcohol may increase the effects of Alprazolam Sandoz.

If you have not told your doctor about any of the above, tell him/her before you start taking Alprazolam Sandoz.

Taking other medicines

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

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

- sleeping tablets, sedatives or tranquillisers
- medicines used to treat depression
- antipsychotics, medicines used to treat certain mental and emotional conditions, e.g. lithium
- medicines used to control epilepsy and fits
- antihistamines, medicines used to prevent or relieve the symptoms of allergy (such as hayfever)
- muscle relaxants
- anaesthetics
- pain relievers
- cimetidine, a medicine commonly used to treat reflux and ulcers
- disulfiram, a medicine used in the treatment of alcoholism
- cyclosporin, an immunosuppressant
- oral contraceptives
- some macrolide antibiotics, e.g. erythromycin or clarithromycin
- some anti-fungal medicines, e.g. ketoconazole or itraconazole
- some medicines used to treat certain heart conditions, e.g. nifedipine, amiodarone, diltiazem
- medicines used to treat HIV infection, e.g. ritonavir.

These medicines may be affected by Alprazolam Sandoz or may affect how well it works. You may need different amounts of your medicines, 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 this medicine.

Also avoid drinking grapefruit juice while taking Alprazolam Sandoz, as it can interact with this medicine.

HOW TO TAKE ALPRAZOLAM SANDOZ

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

They may differ from the information contained in this leaflet.

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

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. This depends on your condition and whether or not you are taking any other medicines.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Alprazolam Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the tablets with a glass of water.

Alprazolam Sandoz can be taken with or without food. However, side effects such as sleepiness may be reduced if you take the tablets immediately after food.

When to take Alprazolam Sandoz

Your doctor will tell you when to take Alprazolam Sandoz.

How long to take Alprazolam Sandoz

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

In general, benzodiazepines such as Alprazolam Sandoz 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 forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

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

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, 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)

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 that you or anyone else may have taken too much Alprazolam Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- drowsiness or feeling tired
- confusion
- dizziness
- difficulty breathing
- feeling weak or fainting.

WHILE YOU ARE TAKING ALPRAZOLAM SANDOZ

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Alprazolam Sandoz.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

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

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 you feel that Alprazolam Sandoz is not helping your condition.

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

Otherwise, your doctor may think it is not effective and change your treatment unnecessarily.

Things you must not do

Do not take Alprazolam Sandoz to treat any other complaints unless your doctor tells you to.

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

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

This medicine may cause drowsiness or dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Even if you take Alprazolam Sandoz at night you may still be drowsy or dizzy the next day.

Do not suddenly stop taking Alprazolam Sandoz if you suffer from epilepsy.

Stopping this medicine suddenly may make your epilepsy worse.

Do not take Alprazolam Sandoz for a longer period than your doctor has prescribed. Do not increase the dosage without first checking with your doctor.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Your doctor may want you to gradually reduce the amount you are taking before stopping completely. This may help reduce the possibility of withdrawal symptoms such as:

- tiredness or difficulty sleeping
- light-headedness
- headache
- abnormal involuntary movement
- nausea or vomiting
- anxiety.

Things to be careful of

Be careful when drinking alcohol while you are taking this medicine.

Combining Alprazolam Sandoz and alcohol can make you more sleepy, dizzy or light-headed. Your doctor may suggest that you avoid alcohol or reduce the amount you drink while you are taking Alprazolam Sandoz.

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 Alprazolam Sandoz.

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.

Do not be alarmed by the following lists of 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, light-headedness
- clumsiness or unsteadiness
- slurred speech
- headache
- gastrointestinal problems.

These side effects are usually mild.

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

- blurred vision
- depression or mood changes
- trouble sleeping, nervousness or anxiety
- tremor or coordination problems
- changes in weight
- memory problems
- irritability, agitation or concentration difficulties
- confusion or hallucinations (seeing, feeling or hearing things that are not there)
- loss of appetite
- impaired sexual function
- irregular menstrual periods
- incontinence or difficulty passing urine.

The above list includes serious side effects that may require medical

attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- unusual feelings of anger, excitement or overactivity
- yellowing of the eyes or skin (jaundice)
- signs of an allergic reaction such as shortness of breath, wheezing or difficulty breathing; swelling of the lips, face, tongue or other parts of the body; rash, itching or hives on the skin.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

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

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

AFTER TAKING ALPRAZOLAM SANDOZ

Storage

Keep your medicine in the original container.

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

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

Do not store Alprazolam Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Alprazolam Sandoz comes in 4 types of tablets:

Alprazolam Sandoz 0.25mg - oval white tablet marked A|25 and arrow symbol.

Alprazolam Sandoz 0.5mg - oval pink tablet marked A|5 and arrow symbol.

Alprazolam Sandoz 1mg - oval light blue tablet marked A|1 and arrow symbol.

Alprazolam Sandoz 2mg - rectangular white tablet marked | A I 2 | and triple scored.

The 0.25mg, 0.5mg and 1mg tablets are available in blisters of 50 tablets.

The 2mg tablets are available in bottles of 50 tablets.

Ingredients

Active ingredients:

- Alprazolam Sandoz 0.25mg - 0.25mg alprazolam
- Alprazolam Sandoz 0.5mg - 0.5mg alprazolam
- Alprazolam Sandoz 1mg - 1mg alprazolam
- Alprazolam Sandoz 2mg - 2mg alprazolam.

Inactive ingredients:

- lactose
- microcrystalline cellulose
- maize starch
- sodium benzoate
- docusate sodium
- povidone

- colloidal anhydrous silica
- sodium starch glycollate
- magnesium stearate
- pigment blend purple (Alprazolam Sandoz 0.5mg only)
- indigo carmine (Alprazolam Sandoz 1mg only).

This medicine does not contain sucrose or gluten.

Supplier

Alprazolam Sandoz is supplied in Australia by:

Sandoz Pty Ltd

ABN 60 075 449 553

19 Harris St

Pymont NSW 2009

Tel: 1800 634 500

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Australian Register Numbers

Alprazolam Sandoz 0.25mg tablets:
AUST R 98663

Alprazolam Sandoz 0.5mg tablets:
AUST R 98664

Alprazolam Sandoz 1mg tablets:
AUST R 98665

Alprazolam Sandoz 2mg tablets:
AUST R 98666