

XANAX[®] TABLETS

Alprazolam (0.25 mg, 0.5 mg, 1 mg)

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What XANAX is used for

XANAX tablets are used to treat

- severe anxiety
- severe anxiety associated with depression
- depression where individuals show loss of interest or depression associated with other diseases
- panic related disorders
- neurotic or reactive depression

XANAX tablets should only be used for short-term treatment of anxiety. The overall duration of treatment should not be more than 12 weeks including a period where the dose is gradually reduced (this is called dose 'tapering').

How XANAX works

XANAX is a tranquilliser containing the active ingredient alprazolam. Alprazolam belongs to one of a group of medicines called benzodiazepines. Benzodiazepines affect chemical activity in the brain and impacts central nervous system function like reduction in anxiety and worry.

Before you use XANAX

- When you must not use it

Do not take XANAX if you:

- Are allergic to alprazolam or other similar benzodiazepine medicines, or to any of the other ingredients (see Section 10 'Product Description' for more details)

Pregnancy and lactation

XANAX may be harmful to the developing baby so you should not take XANAX if you are pregnant or planning to become pregnant.

Tell your doctor immediately if you think you may be pregnant.

Do not breastfeed while taking XANAX, as the drug may pass into breast milk.

Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Talk to your doctor or pharmacist before taking XANAX if you:

- Are pregnant, think you might be pregnant now, are planning to become pregnant or if you are breastfeeding (see also Section Before you use XANAX - When you must not use it for more information).
- If you are taking a group of medicines called opioids.
- If you have ever felt so depressed that you have thought about taking your own life.
- If you have ever suffered any mental illness that requires hospital treatment.
- If you have problems with your lungs, kidneys or liver.
- If you have abused or have addiction to drugs or alcohol in the past or find it difficult to stop taking medicines, drinking or taking drugs.

Your doctor may want to give you special help when you need to stop taking these tablets.

Children and adolescents

Alprazolam is not recommended for children and adolescents under the age of 18 years.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially medicines listed below as the effect of XANAX may be stronger when taken at the same time:

- Any other medicines to treat anxiety or depression or to help you sleep (e.g. nefazodone, fluvoxamine, fluoxetine).
- Some strong pain killers (e.g. propoxyphene).

- Antipsychotic medicines used to treat mental illnesses like schizophrenia.
- Medicines to treat epilepsy.
- Antihistamines for relief or allergies.
- Medicines for treating fungal infections (e.g. ketoconazole, itraconazole).
- Oral contraceptives ('the pill').
- Certain antibiotics (e.g. erythromycin, troleandomycin).
- Cimetidine (for treating stomach ulcers).
- Diltiazem (used for angina and high blood pressure).
- Ritonavir or other similar medicines used for treating HIV.
- Digoxin used for heart problems.

Taking Xanax with an opioid medicine (medicine to relieve pain) can depress your central nervous system. Inform your doctor if you are currently taking any opioid medicine.

Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

If you are going to have an operation where you will be given a general anaesthetic, tell your doctor or anaesthetist that you are taking XANAX.

How to use XANAX

- How much to use

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will tell you how many tablets to take and when to take them. This information is also on the label of the carton the tablets come in. Do not take your tablets with alcohol.

You will usually start by taking a dose of 0.5 mg to 1 mg. This medicine is taken in divided doses two or three times daily.

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The dose may be increased gradually up to a total of 3 mg to 4 mg again taken in divided doses throughout the day.

- When to use it

Use as directed by your doctor or pharmacist.

Adults

Dose should be individualized based upon how severe the symptoms and how the response is by individual patient. When the dose needs to be increased, it is usual to gradually and cautiously increase the dose.

The elderly

If you are an older patient or you have for example kidney or liver problems and you need a lower dose you will normally start on a dose of 250 micrograms twice a day. This dose may be slowly increased if needed and if you don't get any side effects.

Use in children and adolescents

Alprazolam is not recommended for children and adolescents under the age of 18 years.

- How long to use it

Xanax tablets are only used for short-term treatment (not more than 12 weeks including a period where the dose is gradually reduced, this is called dose 'tapering'). You will not normally be given a prescription for more than 4 weeks and you will be regularly reviewed by your doctor during this time.

Stopping treatment

Always see your doctor before you stop taking Xanax tablets as the dose needs to be reduced gradually. If you stop taking the tablets or reduce the dose suddenly you can get 'rebound' effects which might cause you to become temporarily more anxious or restless or to have difficulty sleeping. It is recommended that the daily dosage of alprazolam be decreased by no more than 0.5 mg every 3 days.

Some people may also experience 'withdrawal' effects (see Section Side effects – Dependence and withdrawal symptoms). These symptoms will go away as your body re-adjusts. If you are worried, your doctor can tell you more about this.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you forget to use it

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a missed dose.

- If you use too much (overdose)

It is important that you do not take more tablets than you are told to. If you do accidentally take too many tablets you may experience drowsiness, confusion, feeling cold, slurred speech, motor incoordination, coma and difficulty breathing. If you do accidentally take too many tablets seek medical attention straight away.

While you are using it

- Things you must do

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

- Things you must not do

Taking XANAX with food, drink and alcohol:
It is important not to drink any alcohol while you are taking XANAX, as alcohol increases the effects of the medicine.

- Things to be careful of

Driving and using machines

XANAX can make you feel sleepy and make you lose concentration and so it is very important you do not drive or operate machinery until you know how the tablets affect you.

XANAX contains lactose monohydrate

XANAX contains an ingredient known as lactose monohydrate which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugar contact your doctor before taking this medicinal product.

Side effects

Like all medicines, this medicine can cause side effects although not everyone gets them, and if you do get them they may differ in intensity for different people.

Reasons for seeing your doctor immediately

- Very occasionally treatment with XANAX can cause serious behavioural or psychiatric effects – for example agitation, restlessness, aggressiveness, irritability, violent anger, false beliefs, nightmares and hallucinations or other inappropriate behaviour.
- Sudden wheeziness, difficulty in swallowing or breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).
- If you get any of these symptoms see your doctor straight away as treatment will need to be discontinued. Your doctor will then advise how treatment will be stopped.

Reasons for seeing your doctor as soon as possible

Tell your doctor as soon as possible if you get the following symptoms as your dose or treatment might need to be changed:

- Memory loss (amnesia) or
- Yellowing of the skin and whites of the eye (jaundice)

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Dependence and withdrawal symptoms

- It is possible to become dependent on medicines like XANAX while you taking them which increases the likelihood of getting withdrawal symptoms when you stop treatment.
- Withdrawal symptoms are more common if you:
 - Stop treatment suddenly
 - Have been taking high doses
 - Have been taking this medicine for a long time
 - Have a history of alcohol and drug abuse

This can cause effects such as headaches, muscle pain, extreme anxiety, tension, restlessness, confusion, mood changes, difficulty sleeping and irritability. In severe cases of withdrawal you can also get the following symptoms: nausea (feeling sick), vomiting, sweating, stomach cramps, muscle cramps, a feeling of unreality or detachment, being unusually sensitive to sound, light or physical contact, numbness and tingling of the feet and hands, hallucinations (seeing or hearing things which are not there while you are awake), tremor or epileptic fits. **Please tell your doctor if any withdrawal symptoms get worse or do not go away.**

Other side effects that may occur are: Very common side effects (occurs in more than 1 in 10 patients)

- Sleepiness and drowsiness
- Depression
- Sedation
- Somnolence
- Jerky, uncoordinated movements
- Memory impairment
- Slurred speech
- Dizziness
- Headache
- Constipation
- Dry mouth
- Weakness
- Irritability

Common side effects (occurs in less than 1 in 10 patients)

- Loss of appetite
- Confusion and disorientation

- Changes in your sex drive (men and women)
- Anxiety and nervousness
- Inability to sleep
- Inability to coordinate
- Problems with balance, and unsteadiness (similar to feeling drunk) especially during the day
- Slurred speech
- Loss of alertness or concentration
- Inability to stay awake, feeling sluggish
- Shakiness or trembling
- Double or blurred vision
- Feeling sick
- Skin reactions
- Sexual dysfunction
- Change in your weight

Uncommon side effects (occurs in less than 1 in 100 patients)

- Agitation
- Irregular periods
- Muscle spasms or weakness
- Feeling elated or over-excited, which causes unusual behaviour
- Hallucination (seeing or hearing things that do not exist)
- Feeling hostile and angry
- Difficulty urinating or bladder control problems
- Loss of memory (amnesia)

Other side effects that have been reported, but it is not known how frequently they occur:

- Nervous system imbalance
- In women production of too much prolactin (the hormone that stimulates milk production)
- Being hyperactive
- Feeling hostile or aggressive
- Abnormal thoughts
- Twisting or jerking movements
- Stomach upsets
- Problems with liver function (this shows up in blood tests), inflammation of the liver (hepatitis) and Jaundice
- Sun allergy
- Inability to completely or partially empty the bladder
- Increased pressure inside the eye

- Serious allergic reaction which causes swelling of the face or throat
- Swelling of the ankles, feet or fingers

If you experience any of the above side effects or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of XANAX

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister strip after 'Use before'.

Store below 30°C and in order to protect from light keep your blister strips securely in the outer carton.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Product Description

- What it looks like

XANAX 0.25 mg tablets: White, elliptical full oval scored tablet.
XANAX 0.5 mg tablets: Pink-coloured, elliptical full oval scored tablets.
XANAX 1 mg tablets: Lavender-coloured, elliptical full oval scored tablets.

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- Ingredients**Date of Revision**

08/06/2022

- Active ingredient

The active ingredient is alprazolam.
 Each XANAX 0.25 mg tablet contains 0.25 mg of the active ingredient alprazolam.
 Each XANAX 0.5 mg tablet contains 0.5 mg of the active ingredient alprazolam.
 Each XANAX 1 mg tablet contains 1 mg of the active ingredient alprazolam.

Serial Number

NPRA (R1/5) 07062022/181

PLD-XANAX-0622**- Inactive ingredients**

The other ingredients are:

magnesium stearate,
 microcrystalline cellulose, corn starch, lactose monohydrate, docusate sodium, sodium benzoate, and colloidal anhydrous silica.

The 0.5 mg tablets also contain the colouring agent erythrosine sodium aluminium lake.

The 1 mg tablets also contain the colouring agents erythrosine sodium aluminium lake and FD & C Blue No.2 aluminium lake.

- MAL numbersXANAX[®] 0.25 mg Tablets

MAL05121165ACRSZ

XANAX[®] 0.50 mg Tablets

MAL05121161ACRSZ

XANAX[®] 1 mg Tablets

MAL05121166ACRSZ

Manufacturer

Sanico NV

Turnhout – Belgium

Packaged by:

Pfizer Italia S.R.L

Ascoli Piceno, Italy

Product Registration Holder

Viatris Sdn Bhd

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