

Package leaflet: Information for the patient

Xanax[®] 250 microgram Tablets

Xanax[®] 500 microgram Tablets

Xanax[®] 1 mg Tablets

alprazolam

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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. See section 4.

What is in this leaflet

1. What Xanax is and what it is used for
2. What you need to know before you take Xanax
3. How to take Xanax
4. Possible side effects
5. How to store Xanax
6. Contents of the pack and other information

1. What Xanax is and what it is used for

Xanax contains the active ingredient alprazolam. It belongs to a group of medicines called benzodiazepines (anxiety-relieving medicines).

Xanax is used in adults for treatment of anxiety symptoms which are severe, disabling or causing the patient great distress. This medicine is for short-term use only.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Xanax

Do not take Xanax:

- If you are allergic to alprazolam or other similar benzodiazepine medicines, or to any of the other ingredients of this medicine (listed in section 6).
- If you suffer from a disease called 'myasthenia gravis' where you suffer from very weak and tired muscles.
- If you have severe chest problems or breathing difficulties (e.g. chronic bronchitis or emphysema).
- If you have severe liver problems.
- If you have 'sleep apnoea' - this is a condition where your breathing becomes irregular, even stopping for short periods, while you are asleep.

Warnings and precautions

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 breast-feeding (see also the sections on 'Pregnancy' and 'Breast-feeding' for more information).
- Have ever felt so depressed that you have thought about taking your own life.
- Have ever suffered any mental illness that requires hospital treatment.
- Have problems with your lungs, kidneys or liver.
- Have abused 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 because there have been reports of overdose related deaths.
- There is a risk of developing drug addiction/dependency when using Xanax.
- Have been prescribed medicines for severe anxiety before, because your body can quickly become used to this type of medicine so that it no longer helps you.
- Benzodiazepines and related products should be used with caution in elderly, due to the risk of sedation and / or musculoskeletal weakness that can promote falls, often with serious consequences in this population.

Children and adolescents

Do not give this medicine to children and adolescents below the age of 18 years because safety and efficacy have not been established.

Other medicines and Xanax

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 or the other medicine may change 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. opioids such as morphine, codeine, propoxyphene).
- Antipsychotic medicines used to treat mental illnesses like schizophrenia.
- Medicines to treat epilepsy.
- Antihistamines for relief of allergies.
- Medicines for treating fungal infections (e.g. ketoconazole).
- Oral contraceptives ('the pill').
- Certain antibiotics (e.g. erythromycin).
- Cimetidine (for treating stomach ulcers).
- Diltiazem (used for angina and high blood pressure).
- Digoxin (used to treat various heart conditions).
- Ritonavir or other similar medicines used for treating HIV.

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.

Concomitant use of Xanax and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe Xanax together with opioids the dosage and duration of concomitant treatment should be limited

by your doctor. Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dosage recommendation closely. It could be helpful to inform friends or relatives to be aware of sign and symptoms stated above. Contact your doctor when experiencing such symptoms.

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. Please refer to section 3.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not breast-feed while taking Xanax, as the drug may pass into breast milk.

Driving and using machines

Xanax can make you feel sleepy or woozy 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

This medicine 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 sugars, contact your doctor before taking this medicinal product.

Xanax contains sodium benzoate

This medicine contains 0.11 mg sodium benzoate in each tablet.

Xanax contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Xanax

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.

The recommended dose is:

Adults

You will usually start by taking a dose of 500 micrograms to 1 mg. This medicine is taken in divided doses two or three times daily.

If clinically required your doctor may increase your medicine in small increments. Where the dose does need to be increased, it is usual to increase the night time dose first, before the daytime doses to make sure you are more alert during the day. If you start to get side effects the doctor may lower your 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 do not get any side effects.

Use in children and adolescents

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

Route and/or method of administration

For oral use.

Duration of treatment

The risk of dependency and abuse may increase with the dose and duration of treatment. The doctor will therefore prescribe the lowest effective dose and treatment duration possible, and frequently reassess the need for continued treatment (see section 2 - Warnings and precautions).

The maximum duration of treatment should not be more than 2-4 weeks. Long-term treatment is not recommended. A decreased effect of the drug may develop if used for more than a few weeks.

If you take more Xanax than you should

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, drop in blood pressure and difficulty breathing. If you do accidentally take too many tablets seek medical attention straight away.

If you forget to take Xanax

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 stop taking Xanax

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. Some people may also experience 'withdrawal' effects (see Section 4 – 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.

Your doctor will therefore reduce the dose gradually when the treatment is ended. Dose reduction is done according to individual needs, since gradual discontinuation depends on several factors (e.g. treatment duration and your daily dose). Ask your doctor about how to reduce your dose gradually.

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

4. Possible side effects

Like all medicines this medicine can cause side effects although not everyone gets them.

Reasons for seeing your doctor immediately

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.

- 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).

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)
- Yellowing of the skin and whites of the eyes (jaundice)

Dependence and withdrawal symptoms

It is possible to become dependent on medicines like Xanax while you are 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 long time
- have a history of alcohol or 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: may affect more than 1 in 10 people

- Depression
- Sleepiness and drowsiness
- Jerky, uncoordinated movements
- Inability to remember bits of information
- Slurred speech
- Dizziness, light-headedness
- Headaches
- Constipation
- Dry mouth
- Tiredness
- Irritability

Common: may affect up to 1 in 10 people

- Loss of appetite

- Confusion and disorientation
- Changes in your sex drive (men and women)
- Nervousness or feeling anxious or agitated
- Insomnia (inability to sleep or disturbed sleep)
- Problems with balance, and unsteadiness (similar to feeling drunk) especially during the day
- Loss of alertness or concentration
- Inability to stay awake, feeling sluggish
- Shakiness or trembling
- Double or blurred vision
- Feeling sick
- Skin reactions
- Changes in your weight

Uncommon: may affect up to 1 in 100 people

- Feeling elated or over-excited, which causes unusual behaviour
- Hallucination (seeing or hearing things that do not exist)
- Feeling agitated or angry
- Incontinence
- Cramping pain in the lower back and thighs, which may indicate menstrual disorder
- Muscle spasms or weakness
- Drug addiction
- Drug withdrawal symptoms

Not known: frequency cannot be estimated from the available data

- In women, irregular periods or production of too much prolactin (the hormone that stimulates milk production)
- Feeling hostile or aggressive
- Abnormal thoughts
- Twisting or jerking movements
- Being hyperactive
- Stomach upsets
- Problems with liver function (this shows up in blood tests), inflammation of the liver (hepatitis)
- Nervous system imbalance. Symptoms may include: fast heart beat and unstable blood pressure (feeling dizzy, light-headed or faint)
- Serious allergic reaction which causes swelling of the face or throat
- Swelling of the ankles, feet or fingers
- Skin reaction caused by sensitivity to sunlight
- Difficulty urinating or bladder control problems
- Increased pressure in the eyes, which can also affect your vision
- Drug abuse

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance.
Website: www.hpra.ie.

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal.

5. How to store Xanax

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 'EXP'. The expiry date refers to the last day of that month.

Do not store your tablets above 25°C. Keep the blister in the outer carton.

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 protect the environment.

6. Contents of the pack and other information

What Xanax contains

The active ingredient is alprazolam.

Each Xanax 250 microgram tablet contains 250 micrograms of the active ingredient alprazolam.

Each Xanax 500 microgram tablet contains 500 micrograms of the active ingredient alprazolam.

Each Xanax 1 milligram tablet contains 1 milligram of the active ingredient alprazolam.

The other ingredients are: lactose monohydrate (see section 2 **Xanax contains lactose monohydrate**), microcrystalline cellulose, colloidal anhydrous silica, maize starch, magnesium stearate and docusate sodium with sodium benzoate (see section 2 **Xanax contains benzoate** and **Xanax contains sodium**).

The 500 microgram tablets also contain the colour erythrosine sodium aluminium lake (E127).

The 1 mg tablets also contain the colour indigo carmine aluminium lake (E132) and erythrosine sodium aluminium lake (E127).

What Xanax looks like and contents of the pack

Xanax 250 microgram tablets are white oval tablets scored on one side and marked 'Upjohn 29' on the other.

Xanax 500 microgram tablets are pink oval tablets scored on one side and marked 'Upjohn 55' on the other.

Xanax 1 mg tablets are lavender oval, biconvex tablets scored on one side and marked 'Upjohn 90' on the other.

The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Each tablet strength is available in cartons of 100 tablets.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder(s):

Ireland

Upjohn EESV
Rivium Westlaan 142
2909 LD Capelle aan den IJssel
Netherlands

Malta

Viatrix Hellas Ltd
253-255, Mesogion Avenue,
154 51 Neo Psychiko,
Athens, Greece

Manufacturer:

Pfizer Italia S.r.l.
Localita Marino del Tronto
63100 - Ascoli Piceno (AP)
Italy.

or

Mylan Hungary Kft.
Mylan utca 1
Komárom, 2900
Hungary

or

Fine Foods & Pharmaceuticals N.T.M. S.p.A.
Via Grignano, 43
24041 Brembate (BG)
Italy

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