

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 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 to promote sleep and to reduce anxiety and worry.
- Xanax tablets are only used to treat severe anxiety and severe anxiety associated with depression.

Xanax is not recommended for the treatment of 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’).

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.
- 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

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

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. morphine, codeine, propoxyphene).

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

- 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.

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

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 sugars contact your doctor before taking this medicinal product.

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.

- disorder
- Muscle spasms or weakness

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

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 via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

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 ‘Use before’. 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.

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.

Duration of treatment

- Xanax tablets are only used for short-term treatment (not more than 12 weeks). 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. 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

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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. 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:

Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland.

Manufacturer:

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

Company Contact Address:

For further information on your medicine contact Medical Information at the following address: Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland

Telephone 1800 633 363

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