

## **Package leaflet: Information for the patient**

### **Xanax<sup>®</sup> 250 microgram and 500 microgram Tablets alprazolam**

This medicine contains alprazolam, which can cause dependence, tolerance and addiction. You can get withdrawal symptoms if you stop taking it or reduce the dose suddenly.

#### **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 your pharmacist.
- This medicine has been prescribed for you only. Do not pass it onto 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**

This medicine has been prescribed for you for treatment of anxiety symptoms which are severe, disabling or causing the patient great distress. This medicine is for short-term use only. Xanax contains the active ingredient alprazolam. It belongs to a group of medicines called benzodiazepines.

This medicine has been prescribed to you and should not be given to anyone else.

Benzodiazepines can cause dependence, tolerance and addiction, and you may get withdrawal symptoms if you stop taking it or reduce the dose suddenly. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

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 ‘sleep apnoea’ - this is a condition where your breathing becomes irregular, even stopping for short periods, while you are asleep.
- If you have severe liver problems.
- 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).

### **Warnings and precautions**

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

- Have ever felt so depressed that you have thought about taking your own life.
- Have ever suffered any mental illness that required hospital treatment.
- Have problems with your lungs, kidneys or liver.
- Are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs, or if you have ever had a history of struggling to control your alcohol or drug intake. Your doctor may want to give you special help when you need to stop taking these tablets. There have been reports of death when Xanax is abused with alcohol, prescription medicines or street drugs.
- Have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- 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.
- Feel you need to take more of Xanax to get the same level of symptom control, this may mean you are developing tolerance to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medication.

Taking this medicine regularly, particularly for a long time, can lead to physical dependence and addiction. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months. Physical dependence and addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your tablets suddenly. This could lead to more serious symptoms such as loss of the sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have also experienced numbness or tingling of the arms or legs, tinnitus (ringing sounds in the ears), oversensitivity to light, sound and touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets or stomach pain, loss of appetite, agitation, abnormally fast heartbeats, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very warm, convulsions (sudden uncontrolled shaking or jerking of the body).

Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Benzodiazepines should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of benzodiazepines may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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 or 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 so it is very important you do not operate machinery until you know how the tablets affect you.

Xanax can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - o The medicine has been prescribed to treat a medical or dental problem and
  - o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - o It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

### **Xanax contains Lactose and Sodium Benzoate**

*Lactose* - If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

*Sodium Benzoate* – this medicine contains 0.11mg Sodium Benzoate in each tablet.

### **Information on sodium content**

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 an alcoholic drink.

The recommended dose is:

#### **Adults**

You will usually start by taking one 250 microgram or one 500 microgram tablet three times a day. This gives a total dose of 750 micrograms to 1500 micrograms each day.

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 two or three times 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.

Your doctor will prescribe the lowest possible effective dose and duration, and will reassess the need for your continued treatment frequently. A decreased effect of the drug may develop if used for more than a few weeks.

Your prescriber should have discussed with you how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

**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. These symptoms will go away as your body re-adjusts. If you are worried, your doctor can tell you more about this.

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. This may occur over a period of weeks to months. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Withdrawal symptoms such as: headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your tablets suddenly. This could lead to more serious symptoms such as loss of the sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have also experienced numbness or tingling of the

arms or legs, tinnitus (ringing sounds in the ears), oversensitivity to light, sound and touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets or stomach pain, loss of appetite, agitation, abnormally fast heartbeats, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very warm, convulsions (sudden uncontrolled shaking or jerking of the body).

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 stopping Xanax treatment 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 straight away**

Tell your doctor straight away 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).

##### **Abuse, 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.

When you stop taking Xanax, you may experience drug withdrawal symptoms, which include headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your tablets suddenly. This could lead to more serious symptoms such as loss of the sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have also experienced numbness or tingling of the arms or legs, tinnitus (ringing sounds in the ears), oversensitivity to light, sound and touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets or stomach pain, loss of appetite, agitation, abnormally fast heartbeats, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very warm, convulsions (sudden uncontrolled shaking or jerking of the body).

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.

How do I know if I am tolerant or addicted?

If you notice any of the following signs whilst taking Xanax, it could be a sign that you have become addicted.

- You may feel the need to keep taking the medication for longer than your doctor recommended
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber

Xanax Tablets should only be used by those they are prescribed for. Do not give your medicine to anyone else. Overuse and abuse can lead to overdose and/or death.

**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
- Increased sex drive (men and women) and erectile dysfunction
- 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
- Change 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 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)
- Imbalance to part of nervous system. 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
- Dependence and addiction (see section “How do I know if I am tolerant or addicted?”).

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 or bottle after ‘EXP’. The expiry date refers to the last day of that month.

Do not store your tablets above 25°C. Store in the original package in order to protect from moisture.

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.

The other ingredients are: lactose (section 2 Xanax contains lactose), microcrystalline cellulose, colloidal anhydrous silica, maize starch, magnesium stearate and docusate sodium with sodium benzoate (E 211). The 500 microgram tablets also contain the colour erythrosine sodium aluminium lake.

### **What Xanax looks like and contents of the pack**

Xanax 250 microgram tablets are white, oval, biconvex tablets scored on one side and marked 'Upjohn 29' on the other. Xanax 500 microgram tablets are pink, oval, biconvex tablets scored on one side and marked 'Upjohn 55' on the other. They are available in blister packs of 60 tablets or bottles containing 100 or 1000 tablets. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder:

Viatrix Products Limited,  
Station Close,  
Potters Bar,  
EN6 1TL,  
United Kingdom.

Manufacturer:

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