

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Xanax® XR 0.5 mg
Xanax® XR 1 mg
Xanax® XR 2 mg
Sustained-release tablets



Active ingredient and its quantity:
Each sustained-release tablet contains:
alprazolam 0.5 mg, 1 mg, 2 mg

For a list of inactive ingredients and allergens, see section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Further information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

Xanax® XR is a psychotropic medication containing alprazolam, that can be abused or lead to dependence. Inform your doctor if you currently abuse or have previously abused or developed a dependence on alcohol, prescription medicines or drugs. Giving away or selling the medicine may harm others and is against the law. Keep the medicine in a safe place and away from children.

<p>What is important to know about Xanax® XR?</p> <ul style="list-style-type: none">• This medicine belongs to the benzodiazepine group, which has special characteristics that require extra caution when using it.• Taking this medicine with medicines of the opioid group, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma and death. Get emergency help right away if any of the following happens:<ul style="list-style-type: none">• shallow or slowed breathing• breathing stops (may lead to the heart stopping)• excessive sleepiness (sedation)Do not drive or operate dangerous machines until you know how this medicine affects you.• Risk of abuse, misuse and addiction. There is a risk of abuse, misuse and addiction with use of benzodiazepines, including Xanax® XR, which can lead to overdose and serious side effects, including coma and death.• Serious side effects, including coma and death, have happened in people who have abused or misused benzodiazepines, including Xanax® XR. These serious side effects may also include delirium, paranoia, suicidal thoughts or actions, seizures, and difficulty breathing. Contact your doctor or go to the nearest hospital emergency room right away if you experience any of these serious side effects.• You can develop an addiction to Xanax® XR even if you take it as prescribed by your doctor.• Physical dependence and withdrawal reactions. Xanax® XR can cause physical dependence and withdrawal reactions. Do not suddenly stop treatment with Xanax® XR. Stopping treatment with Xanax® XR suddenly can cause serious and life-threatening side effects. Including, unusual movements, responses, or expressions, seizures, sudden and severe mental or nervous system changes, depression, seeing or hearing things that others do not see or hear, an extreme increase in activity or talking, losing touch with reality, and suicidal thoughts or actions. Contact a doctor or go to the nearest emergency room right away if you experience any of the following symptoms.• Some patients who suddenly stop treatment with benzodiazepines, have symptoms that can last for several weeks to more than 12 months, including anxiety, trouble remembering, learning, or concentrating, depression, problems sleeping, feeling like insects are crawling under your skin, weakness, shaking, muscle twitching, burning or pricking feeling in your hands, arms, legs or feet, and ringing in your ears.• Physical dependence is not the same as drug addiction. The doctor can tell you more about the differences between them.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Xanax® XR is used for the treatment of anxiety, anxiety associated with depression and panic disorders, with or without phobic avoidance.

Therapeutic group:
benzodiazepines.

Xanax® XR belongs to the benzodiazepine group, and acts on GABA receptors in the brain.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to alprazolam or to any of the other ingredients in this medicine (see section 6) or to other medicines in the benzodiazepine group.
- you are taking medicines to treat fungal infections such as ketoconazole and itraconazole.

Special warnings regarding use of the medicine
Before treatment with Xanax® XR, tell your doctor if:

- you have or have had depression, mood problems, suicidal thoughts or behavior
- you have liver or kidney problems
- you have lung disease or breathing problems
- you are pregnant or plan to become pregnant. Xanax® XR may harm your unborn baby. You should consult your doctor about taking Xanax® XR while you are pregnant.
- you are breastfeeding or plan to breastfeed. The medicine passes into your breast milk and may harm your baby. Consult your doctor about the most appropriate way to feed your baby if you take Xanax® XR. Do not use this medicine if you are breastfeeding.

Additional warnings

Close medical monitoring is very important when taking this medicine. See section: 'What is important to know about Xanax® XR?' in the beginning of this leaflet.
Taking this medicine with medicines of the opioid group and other medicines, a risk of abuse, misuse and addiction; physical dependence and withdrawal effects.

Children and adolescents

This medicine is not intended for children and adolescents below the age of 18. There is no information regarding the safety and effectiveness of this medicine in children.

The elderly

Elderly patients are especially susceptible to dose related adverse effects when taking the medicine. It is advisable to consult your doctor before beginning treatment.

Drug interactions

If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Do not use together with medicines for fungal infections such as ketoconazole and itraconazole. See section 2.

- Opioids such as morphine, buprenorphine, hydromorphone, oxycodone, fentanyl, methadone, alfentanil, butorphanol, codeine, dihydrocodeine, meperidine, pentazocine, remifentanyl, sufentanil, tapentadol, tramadol. The combination with Xanax® XR may increase the risk of respiratory depression.
- Do not drink alcohol or take other medicines that may make you feel sleepy or dizzy while taking Xanax® XR without consulting your doctor. In combination with other medicines that cause sleepiness or dizziness, Xanax® XR may make your sleepiness or dizziness worse.

See 'What is important to know about Xanax® XR?' at the beginning of this leaflet.

In particular, inform your doctor or pharmacist if you are taking:

- Medicines to treat anxiety and depression (nefazodone, fluvoxamine, fluoxetine, sertraline, paroxetine)
- Cimetidine (for ulcer)
- Medicines to treat HIV infection such as ritonavir
- Birth control pills

Medicines that affect the central nervous system such as antipsychotics, anticonvulsants such as phenytoin, carbamazepine; medicines to treat allergy (antihistamines) and ethanol

Using this medicine and alcohol consumption

Do not consume any alcohol during treatment with the medicine. Alcohol consumption can increase your risk of having serious side effects.

Pregnancy, breastfeeding, and fertility
If you are pregnant or planning to become pregnant, you should consult with your doctor, as this medicine may harm the unborn baby.

If you are breastfeeding or planning to breastfeed, consult with your doctor. The medicine passes into your breast milk and may harm your baby. Do not use this medicine if you are breastfeeding.

Driving and using machines

Xanax® XR can make you sleepy or dizzy and can slow your thinking and motor skills.
Do not drive or operate dangerous machines until you know how this medicine affects you.

Important information about some of this medicine's ingredients

Xanax® XR tablets contain lactose. If your doctor has told you that you are sensitive to certain sugars such as lactose, contact your doctor before using this medicine.

3. HOW TO USE THIS MEDICINE?

Always use this preparation according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by your doctor only.

Do not use Xanax® XR for conditions other than the one for which it was prescribed.

Do not give Xanax® XR to others, even if they have the same symptoms that you have. It may harm them.

The standard dosage is usually: To begin treatment: 0.5-1 mg once daily, preferably in the morning.

Do not exceed the recommended dose! Do not take more Xanax® XR than prescribed or take it for longer than prescribed for you.

Do not increase the dosage even if you think the medicine "no longer works" without consulting the doctor. Benzodiazepines, even when taken according to the doctor's instructions, can cause emotional and/or physical dependence.

Do not stop taking the medicine suddenly or lower the dosage without consulting your doctor, since withdrawal symptoms may occur.

Some of the patients may experience difficulty stopping treatment with Xanax® XR because of severe emotional and physical dependence. It is important to consult with your doctor in order to stop treatment carefully and safely. Proper cessation of treatment will help lessen the possibility of withdrawal reactions that can vary from mild reactions to severe reactions such as an attack.

Swallow the tablet whole.

Do not crush/split/chew, since the tablets are sustained-release tablets, and the active ingredient has to be gradually released from them over an extended period of time.

Keep Xanax® XR in a safe place to prevent overuse and abuse and out of the reach of children.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately go to a hospital emergency room, and bring the medicine package with you.

If you forget to take this medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them. If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Xanax® XR, may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Important side effects

- Effects related to use of this medicine with medicines of the opioid group and other medicines, risk of abuse, misuse and addiction; physical dependence and withdrawal effects, see: 'What is important to know about Xanax® XR?' at the beginning of this leaflet.
- **Seizures.** The medicine can cause seizures and seizures that will not stop (status epilepticus).
- **Mania.** The medicine may cause an increase in activity and talking (mania and hypomania) in people who have depression.

The most common side effects:

Sedation, sleepiness, trouble saying words clearly (dysarthria), depression, problems with coordination, problems with memory, changes in sex drive (libido) constipation, nausea and tiredness.

Common side effects (effects that appear in 1-10 in 100 users):

Palpitations, vertigo, blurred vision, diarrhea, vomiting, digestion difficulties, abdominal pain, malaise, weakness, chest pain, back pain, muscle cramps and twitching, headache, dizziness, tremor, irritability, insomnia, nervousness, derealization, restlessness, agitation, depersonalization (feeling detached), nightmares, difficulty passing urine, nasal congestion, hyperventilation, increased sweating, problems with coordination, mental impairment, ataxia, disturbance in attention, balance impairment, excessive movement (dyskinesia), loss of sensation (hypoesthesia), increased sleep, lethargy, disorientation, confusion, depressed mood, increased appetite, anorexia, weight gain, road traffic accidents, menstrual pain (dysmenorrhea), sexual dysfunction, joint pain (arthralgia), muscle pain (myalgia), pain in limbs.

Uncommon side effects (effects that appear in 1-10 in 1,000 users):

Rapid heartbeat (tachycardia), tinnitus, ear pain, dilation of the pupil, photophobia (intolerance of light), difficulty swallowing, increased secretion of saliva, falls, high fever, feeling thirsty, feeling hot and cold, edema, feeling jittery, sluggishness, fatigue, feeling drunk, chest tightness, increased energy, feeling of relaxation, hangover, loss of control of legs, chills, amnesia, clumsiness, syncope, hypotonia, seizures (convulsions), depressed level of consciousness, sleep apnea syndrome, sleep talking, stupor, abnormal dreams, apathy, aggression and anger, slowness of thought, sense of euphoria, excessive and irrational talk, mood swings, difficulty speaking, hallucinations, homicidal thoughts, mania, hypomania uncontrolled impulses, psychomotor retardation, suicidal thoughts, urinary frequency, urinary incontinence, choking sensation, nosebleed, runny nose, clammy skin, rash urticaria, hypotension.

Side effects of unknown frequency:

Increase in liver enzymes, hepatitis, jaundice, liver failure, peripheral edema, irregular menstrual period, high prolactin level, gynecomastia (increased breast tissue in men), galactorrhea (breast milk production not connected to birth), Stevens-Johnson syndrome, angioedema, photosensitivity reaction.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 30°C

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

lactose, methylhydroxypropylcellulose, colloidal anhydrous silica, magnesium stearate, FD&C blue # 2 (in 0.5 mg and 2 mg tablets)

Each tablet contains 221.7 mg lactose.

See section 2 'Important information about some of this medicine's ingredients'.

What the medicine looks like and contents of the pack:

Each box contains 30 tablets
Xanax® XR 0.5 mg: a round, convex, blue tablet with "P&U 57" imprinted on one side.
Xanax® XR 1 mg: a round, convex, white tablet with "P&U 59" imprinted on one side.
Xanax® XR 2 mg: a pentagonal, blue tablet with "P&U 66" imprinted on one side.

Registration holder and address:

Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
Xanax® XR 0.5 mg: 110-49-28804
Xanax® XR 1 mg: 110-50-28805
Xanax® XR 2 mg: 110-51-28806

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