

PRAZOVEX TABLET

Alprazolam (0.25mg, 0.5mg)

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What Prazovex is used for

Prazovex tablets are only used to treat severe anxiety and severe anxiety associated with depression. Prazovex is not recommended for the treatment of depression.

Prazovex 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 Prazovex works

Prazovex 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.

Before you use Prazovex

- When you must not use it

Do not take Prazovex if you:

- are allergic to alprazolam or other similar benzodiazepine medicines, or to any of the other ingredients
- suffer from a disease called 'myasthenia gravis' where you suffer from very weak and tired muscles
- have severe chest problems or breathing difficulties (e.g. chronic bronchitis or emphysema)
- have severe liver problems
- have 'sleep apnoea' - this is a condition where your breathing becomes irregular, even stopping for short periods, while you are asleep
- are pregnant, think you might be pregnant now, are planning to become pregnant or if you are breast-feeding

- Before you start to take it

Tell your doctor if you have any of these following conditions. If you:

- have ever felt so depressed that you have thought about taking your own life.
- have ever suffered any mental illness that requires hospital treatment.
- are under 18 years old.
- 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.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any of the following medicines, as the effect of Prazovex may be stronger when taken at the same time:

- any other medicines to treat anxiety or depression or to help you sleep.
- some strong pain killers (e.g. morphine or codeine).
- 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 chest pain and high blood pressure).
- 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 Prazovex.

Taking Prazovex 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.

How to use Prazovex

- How much to use

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. If you are not sure, check with your doctor or pharmacist. Do not take your tablets with an alcoholic drink.

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.

This may be increased gradually up to a total of 3000 micrograms (3mg) a day in divided doses throughout the day.

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 don't get any side effects.

Children

Prazovex is not recommended for the treatment of children and teenagers.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to take it

Prazovex 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.

Always see your doctor before you stop taking Prazovex tablets as the dose needs to be reduced gradually. If you

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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.

- **If you forget to take 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 take 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, seek medical attention straight away.

While you are using it

- **Things you must do**

Prazovex contains an ingredient known as lactose 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.

- **Things you must not do**

It is important not to drink any alcohol while you are taking Prazovex, as alcohol increases the effects of the medicine.

Prazovex may be harmful to the developing baby so you should not take Prazovex if you are pregnant or planning to become pregnant, tell your doctor immediately.

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

- **Things to be careful of**

Driving and using machinery

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

Side Effects

Like all medicines Prazovex 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 stopping Prazovex treatment immediately

- Very occasionally treatment with Prazovex 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 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) or
- yellowing of the skin and whites of the eyes (jaundice)

Dependence and withdrawal symptoms

- It is possible to become dependent on medicines like Prazovex 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 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.

Other side effects that may occur are:

Tell your doctor or pharmacist if you experience any of these side effects.

- Loss of alertness or concentration
- Tiredness
- Insomnia (inability to sleep or disturbed sleep)
- Sleepiness and unsteadiness (similar to feeling drunk) especially during the day
- Light-headedness
- Nervousness or feeling anxious
- Confusion
- Double or blurred vision
- Increased pressure in the eyes, which can also affect your vision
- Shakiness or trembling
- Slurred speech
- Stomach upsets
- Loss of appetite or change in your weight
- Muscle spasms or muscle weakness
- Jerky, uncoordinated movements
- Headaches
- Difficulty urinating or bladder control problems
- Dizziness
- Skin reactions
- Problems with liver function (this shows up in blood tests)
- In women, irregular periods or production of too much prolactin (the hormone that stimulates milk production)
- Changes in your sex drive (men and women)

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 Prazovex

- **Storage**

Keep them out of the reach of the children.

Do not store in temperature over 30°C. Keep it in its original pack. Protect it from light and humidity. Do not use it after its expiring date, recorded on the packaging.

- **Disposal**

Medicines should not be disposed of via wastewater or household waste.

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Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Prazovex 0.25mg tablets are white, concave, round, scored tablets.

Prazovex 0.5mg tablets are white, concave, round, scored tablets.

- Ingredients

- Active ingredient:

Alprazolam

- Inactive ingredients:

lactose, potato starch, polyvidone, microcrystalline cellulose, chloroform, methanol, talc, magnesium stearate, docusate sodium and purified water

- MAL number:

0.25mg: MAL08031377ACZ

0.5mg: MAL08042466ACZ

Manufacturer

Delorbis Pharmaceuticals Ltd.,
17 Athinon Street,
Ergates Industrial Area,
2643 Ergates, Lefkosia,
Cyprus.

Product Registration Holder

Apex Pharmacy Marketing Sdn Bhd
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Malaysia.

Date of Revision

30/08/2023

Serial Number

NPRA (R2/1)190610/160