

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 more 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.

ANAXAL® 0,25 mg, 0,5 mg and 1 mg Tablets *Alprazolam*

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What is in this leaflet

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

1. What ANAXAL is and what it is used for

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

Do not take **ANAXAL**:

- 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 or 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 **ANAXAL** 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.
 - 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

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 ANAXAL

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 **ANAXAL** 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 **ANAXAL**. Concomitant use of **ANAXAL** 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 **ANAXAL** 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.

ANAXAL with food, drink and alcohol

It is important not to drink any alcohol while you are taking **ANAXAL**, 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 **ANAXAL**, as the drug may pass into breast milk.

Driving and using machines

ANAXAL 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.

ANAXAL 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:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information
 - provided with the medicine and
 - 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.

3. How to take ANAXAL

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

ANAXAL 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 **ANAXAL** 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 **ANAXAL**

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 **ANAXAL**

Always see your doctor before you stop taking **ANAXAL** 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.

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 **ANAXAL** 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 **ANAXAL** 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).

Dependence and withdrawal symptoms

It is possible to become dependent on medicines like **ANAXAL** 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.

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

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

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ANAXAL

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 expiration date. 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 ANAXAL contains

The active ingredient is alprazolam.

Each **ANAXAL** 0,25 mg tablet contains 250 micrograms of the active ingredient alprazolam.

The other ingredients are: Lactose monohydrate, microcrystalline cellulose, DSS 85%, pregelatinized starch, crospovidone, colloidal silica, magnesium stearate.

Each **ANAXAL** 0,5 mg microgram tablet contains 500 micrograms of the active ingredient alprazolam.

The other ingredients are: Lactose monohydrate, microcrystalline cellulose, DSS 85%, pregelatinized starch, crospovidone, colloidal silica, magnesium stearate, Topmill red.

Each **ANAXAL** 1 mg tablet contains 1 milligram of the active ingredient alprazolam.

The other ingredients are: Lactose monohydrate, microcrystalline cellulose, DSS 85%, pregelatinized starch, crospovidone, colloidal silica, magnesium stearate. Topmill blue.

What ANAXAL looks like and contents of the pack

ANAXAL 0,25 mg tablets

Box with 30 tablets (uniformed, rounded, slightly biconvex tablets, white, with break line on one side) of 0,25 mg alprazolam in blister packs.

ANAXAL 0,5 mg tablets

Box with 30 tablets (uniformed, rounded, slightly biconvex tablets, light pink, with break line on one side) of 0,5 mg alprazolam in blister packs.

ANAXAL 1 mg tablets

Box with 30 tablets (uniformed, rounded, slightly biconvex tablets, light blue, with break line on one side) of 0,5 mg alprazolam in blister packs.

Marketing Authorisation Holder and Manufacturer

ZADA Pharmaceuticals Ltd.
Donji Bistarac without number
75 300 Lukavac
Bosnia and Herzegovina

Date and number of last renewal of marketing authorization:

ANAXAL 0,25 mg tablets, 30 x 0,25 mg:
Number: 04-07.3-2-2406/16 **Date:** 02.03.2017.

ANAXAL 0,5 mg tablets, 30 x 0,5 mg:
Number: 04-07.3-2-2407/16 **Date:** 02.03.2017.

ANAXAL 1 mg tablets, 30 x 1 mg:
Number: 04-07.3-2-2408/16 **Date:** 02.03.2017.

This leaflet was last revised in: 03/2018