

## **Arrow - Alprazolam**

Alprazolam 0.25 mg, 0.5 mg, 1.0 mg, 2.0 mg Tablets

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### **What is in this leaflet**

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This leaflet answers some common questions about ARROW - ALPRAZOLAM.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking ARROW - ALPRAZOLAM against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

**Keep this leaflet with your medicine.** You may need to read it again.

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### **What ARROW - ALPRAZOLAM is used for**

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ARROW - ALPRAZOLAM contains alprazolam. It belongs to a group of medicines called benzodiazepines. These medicines are thought to work by their action on some brain chemicals. ARROW - ALPRAZOLAM is used to treat anxiety and some depressive symptoms associated with anxiety.

In general, benzodiazepines such as ARROW - ALPRAZOLAM should be taken for short periods only (eg 2 to 4 weeks). Continuous long term use is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on the medicine.

Your doctor may have prescribed ARROW - ALPRAZOLAM for another reason. **Ask your doctor if you have any questions about why ARROW - ALPRAZOLAM has been prescribed for you.**

ARROW - ALPRAZOLAM is not recommended for use in children under 18 years of age, as the safety and effectiveness of alprazolam in this group have not been established.

ARROW - ALPRAZOLAM is available only with a doctor's prescription.

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### **Before you take ARROW - ALPRAZOLAM**

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***When you must not take it***

**Do not take ARROW - ALPRAZOLAM if you are allergic to medicines containing alprazolam, other benzodiazepines or any of the ingredients**

**listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- lumpy skin rash ('hives'), hayfever or fainting.

**Do not take ARROW - ALPRAZOLAM if you have:**

- severe muscle weakness known as myasthenia gravis
- severe and chronic lung disease.

**Do not take ARROW - ALPRAZOLAM if the expiry date (Exp.) printed on the pack has passed.**

**Do not take ARROW - ALPRAZOLAM if the packaging shows signs of tampering or the tablets do not look quite right.**

**Before you start to take it**

**Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.**

**Tell your doctor if you are pregnant or plan to become pregnant.**

Your doctor will discuss the risks and benefits of taking ARROW - ALPRAZOLAM during pregnancy.

**Tell your doctor if you are breastfeeding or plan to breastfeed.**

Alprazolam can pass into breast milk. Your doctor will discuss the risks and benefits of taking ARROW - ALPRAZOLAM when breastfeeding.

**Tell your doctor if you have any medical conditions, especially the following:**

- depression, psychosis or schizophrenia
- liver, kidney or lung disease
- suffering from fits or convulsions
- glaucoma (high pressure in the eye)
- myasthenia gravis (severe muscle weakness)
- low blood pressure
- previous problems with addiction to medicine.

**Tell your doctor if you drink alcohol regularly.**

Alcohol may increase the effects of ARROW - ALPRAZOLAM.

**If you have not told your doctor about any of the above, tell him/her before start taking ARROW - ALPRAZOLAM.**

**Taking other medicines**

**Tell your doctor if you are taking any other medicines, including those you buy without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines may be affected by ARROW - ALPRAZOLAM, or may affect how well it works. These include:

- sedatives, medicines used to produce calmness or to help you sleep
- medicines to control epilepsy or fits
- antipsychotics, medicines used to treat certain mental and emotional conditions
- medicines for depression
- muscle relaxants
- antihistamines, medicines used to prevent or relieve the symptoms of allergy such as hayfever
- some pain relievers
- anaesthetics
- cimetidine, a medicine used to treat reflux and ulcers
- some macrolide antibiotics, eg erythromycin
- antifungal agents, eg ketoconazole
- oral contraceptives
- HIV protease inhibitors, medicines used to treat HIV infection
- lithium, a medicine used to treat mood swings and some types of depression
- disulfiram, a medicine used to treat alcoholism
- atropine and similar medicines.

Your doctor can tell you what to do if you are taking any of these medicines

**If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.**

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ARROW - ALPRAZOLAM.

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## **How to take ARROW - ALPRAZOLAM**

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

### ***How much to take ARROW - ALPRAZOLAM***

The dose varies from patient to patient. Your doctor will tell you how many tablets you need to take and when to take them. This depends on your condition and whether or not you are taking any other medicines.

### ***How to take ARROW - ALPRAZOLAM***

Swallow the tablets with a glass of water. The tablets can be taken with or without food. However, side effects such as sleepiness or drowsiness may be reduced if you take your tablets immediately after meals.

### ***How long to take ARROW - ALPRAZOLAM***

**Keep taking ARROW - ALPRAZOLAM for as long as your doctor recommends.**

In general, benzodiazepines like ARROW - ALPRAZOLAM should be taken for short periods only (eg 2 to 4 weeks). Continuous long term use is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on the medicine.

### ***If you forget to take ARROW - ALPRAZOLAM***

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.**

**Do not take a double dose to make up for the dose you missed.**

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you take too much ARROW - ALPRAZOLAM (overdose)**

**Immediately telephone your doctor, or the National Poisons Information Centre (0800 POISON or 0800 764 766), or go to the Accident and Emergency department at your nearest hospital, if you think that you or anyone else may have taken too many ARROW - ALPRAZOLAM.**

**Do this even if there are no signs of discomfort or poisoning. Also, make sure you report if any other medicines and/or alcohol that have been taken at the same time with ARROW - ALPRAZOLAM.**

You may need urgent medical attention.

If you take too much ARROW - ALPRAZOLAM, you may feel drowsy, tired, confused and dizzy, have difficulty breathing, feel weak or become unconscious.

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## **While you are taking ARROW - ALPRAZOLAM**

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### **Things you must do**

**Before starting any new medicine, tell your doctor or pharmacist that you are taking ARROW - ALPRAZOLAM.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking ARROW - ALPRAZOLAM.**

**If you become pregnant while taking ARROW - ALPRAZOLAM, tell your doctor.**

**Visit your doctor regularly, so he/she can check on your progress.**

Your doctor will check your condition to see whether you should continue to take ARROW - ALPRAZOLAM.

**Tell your doctor if, for any reason, you have not taken ARROW - ALPRAZOLAM exactly as prescribed.**

Otherwise, your doctor may think that it is not effective and change your treatment unnecessarily.

**Tell your doctor if you feel that ARROW - ALPRAZOLAM is not helping your condition.**

**Always discuss with your doctor any problems or difficulties you may have and how you feel, especially if your anxiety attacks are getting worse or more frequent during or after taking ARROW - ALPRAZOLAM.**

This will help your doctor to determine the best treatment for you.

### ***Things you must not do***

**Do not drive or operate machinery until you know how ARROW - ALPRAZOLAM affects you.**

ARROW - ALPRAZOLAM may cause drowsiness or dizziness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

If you take ARROW - ALPRAZOLAM at night, you may still be drowsy or dizzy the next day.

**Do not take ARROW - ALPRAZOLAM for a longer period of time than your doctor has prescribed.**

ARROW - ALPRAZOLAM should be taken for short periods only (eg 2 to 4 weeks), unless advised otherwise by your doctor.

**Do not increase your dose of ARROW - ALPRAZOLAM without first checking with your doctor.**

**Do not stop taking ARROW - ALPRAZOLAM, or lower the dose, without first checking with your doctor.**

Stopping this medicine suddenly may cause some unwanted effects. Your doctor will slowly reduce your dose before you can stop taking it completely. This may help reduce the possibility of unwanted side effects.

**Do not use ARROW - ALPRAZOLAM to treat any other conditions unless your doctor tells you to.**

**Do not give ARROW - ALPRAZOLAM to anyone else, even if they have the same condition as you.**

**Things to be careful of**

**Be careful with drinking alcohol while taking ARROW - ALPRAZOLAM.**

Combining ARROW - ALPRAZOLAM and alcohol can make you more sleepy, dizzy or light-headed.

Your doctor may suggest that you avoid alcohol or reduce the amount you drink while you are taking ARROW - ALPRAZOLAM.

**Be careful if you are elderly, unwell or taking other medicines.**

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ARROW - ALPRAZOLAM.**

Like other medicines, ARROW - ALPRAZOLAM may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you.**

The most common side effects of ARROW - ALPRAZOLAM are:

- drowsiness

- dizziness
- light-headedness.

Less common side effects are blurred vision, headache, depression, trouble sleeping, nervousness or anxiety, tremor, change in weight, memory problems, co-ordination problems, gastrointestinal and nervous system problems, skin rash, stimulation, agitation, concentration difficulties, confusion, hallucinations, irritability, loss of appetite, problems with muscle tone, fatigue, slurred speech, yellowing of the skin and/or eyes, musculoskeletal weakness, changes in libido, impotence, irregular menstrual periods, incontinence, inability or difficulty passing urine and liver problems. Pressure in the eye is a rare side effect.

**Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following after taking ARROW - ALPRAZOLAM:**

- lumpy, itchy skin rash ('hives') or severe skin reactions
- swelling of the face, mouth, throat or limbs
- chest tightness or pain, shortness of breath, wheezing or difficulty breathing.

These may be symptoms of an allergic reaction to the tablets.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known. Tell your doctor if you notice anything that is making you feel unwell.

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## **After taking ARROW - ALPRAZOLAM**

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### ***Storage***

**Keep ARROW - ALPRAZOLAM where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Keep your tablets in the blister packs in a cool, dry place where the temperature stays below 25°C. Keep your bottles of tablets in a cool, dry place where the temperature stays below 30°C.**

**Do not store ARROW - ALPRAZOLAM or other medicines in the bathroom or near a sink.** Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

### ***Disposal***

If your doctor tells you to stop taking ARROW - ALPRAZOLAM, or your tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

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## Product description

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### *What it looks like*

ARROW - ALPRAZOLAM comes in four strengths of tablets:

- ARROW - ALPRAZOLAM 0.25 - oval, convex white tablet marked 'A|25' and '>'
- ARROW - ALPRAZOLAM 0.5 - oval, convex pink tablet marked 'A|5' and '>'
- ARROW - ALPRAZOLAM 1 - oval, convex light blue tablet marked 'A|1' and '>'
- ARROW - ALPRAZOLAM 2 - rectangular white tablet marked '|A | 2|' and triple scored.

ARROW - ALPRAZOLAM 0.25 mg, 0.5 mg and 1 mg tablets are available in both blister packs and bottles of 50 tablets. ARROW - ALPRAZOLAM 2 mg tablets are available in bottles of 50 tablets.

### *Ingredients*

The active ingredient in ARROW - ALPRAZOLAM is alprazolam:

- each ARROW - ALPRAZOLAM 0.25 tablet contains 0.25 mg of alprazolam
- each ARROW - ALPRAZOLAM 0.5 tablet contains 0.5 mg of alprazolam
- each ARROW - ALPRAZOLAM 1 tablet contains 1 mg of alprazolam
- each ARROW - ALPRAZOLAM 2 tablet contains 2 mg of alprazolam.

The tablets also contain

- lactose
- microcrystalline cellulose
- maize starch
- sodium benzoate
- docusate sodium
- povidone
- colloidal anhydrous silica
- sodium starch glycollate
- magnesium stearate
- Pigment Blend Purple PB20026 (only in ARROW - ALPRAZOLAM 0.5 mg tablets)
- Indigo Carmine CI73015 (only in ARROW - ALPRAZOLAM 1 mg tablets).

The tablets do not contain gluten, sucrose, tartrazine or any azo dyes.

***Supplier***

ARROW - ALPRAZOLAM is distributed in New Zealand by:

**Arrow Pharmaceuticals (NZ) Limited**

Mount Eden Central Business Park  
33a Normanby Road, Mt Eden  
Auckland, New Zealand.

***Date of preparation***

25 August 2010