

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Alprazolam 0.25 mg, 0.5 mg, 1.0 mg Tablets alprazolam

**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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What alprazolam is and what it is used for
2. Before you take alprazolam
3. How to take alprazolam
4. Possible side effects
5. How to store alprazolam
6. Further information

### **1. WHAT ALPRAZOLAM IS AND WHAT IT IS USED FOR**

Your tablets contain alprazolam, which belongs to a group of medicines called benzodiazepines. Alprazolam is believed to increase the actions of a naturally occurring substance, called GABA, within the brain. Alprazolam is used for short-term treatment of severe anxiety disorder. Treatment with alprazolam should only be used short term as it can lead to dependence.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ALPRAZOLAM**

#### **Do not take Alprazolam**

- if you are allergic (hypersensitive) to alprazolam, benzodiazepines or any of the other ingredients of alprazolam Tablets
- if you suffer from a condition called myasthenia gravis which causes the muscles to be weak
- if you have taken benzodiazepine medicine before and suffered an unusual or allergic reaction to it
- if you suffer from breathing difficulties or lung disease
- if you suffer from sleep apnoea syndrome (irregular breathing whilst sleeping)
- if you have severe liver problems
- if you suffer from alcoholism or drug abuse
- if you are taking other medication known to affect the central nervous system (e.g. benzodiazepines, neuroleptics)
- if you suffer from glaucoma

#### **Take special care with Alprazolam**

- if you suffer from lung, liver or kidney problems
- if you suffer from depression or anxiety associated with depression, as alprazolam may increase any suicidal feelings you may have
- if you are taking other medicine to help anxiety or insomnia
- if you 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 to stop taking these tablets
- if you suffer from a personality disorder
- if you notice any changes in your behaviour as alprazolam has been associated with unusual reactions such as restlessness, agitation, irritability, aggressiveness, delusion, rages, nightmares,

hallucinations, psychoses and odd behaviour. If this happens to you, **please speak to your doctor, as your medicine will need to be stopped.**

### **Other medicines and Alprazolam**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. It is especially important to tell your doctor if you are using the following medicines:

- Medicines to treat anxiety, depression or to help you sleep, such as imipramine and desimipramine, as these may increase the effects of alprazolam
- Anti-psychotics, hypnotics, sedatives, narcotics analgesics like propoxyphene or antidepressants, as these can also increase the effects of alprazolam
- Medicine to treat mental illness like schizophrenia (clozapine or nefazodone)
- Any antidepressants known as Selective Serotonin Re-uptake Inhibitors (SSRIs) like fluoxetine and sertraline (used to treat depression)
- Medicine to treat epilepsy
- Medicine for allergies (antihistamines)
- Medicines for treating fungal infections (ketoconazole, itraconazole and otherazole derivatives)
- Cimetidine (for treating stomach ulcers), nefazodone (for treating depression) or fluvoxamine (for treating Obsessive Compulsive Disorders OCD), as your dose of alprazolam may need to be adjusted
- Oral contraceptives (the "PILL")
- Diltiazem (used for angina and high blood pressure)
- Certain antibiotics e.g. erythromycin, troleandomycin
- Medicine used to treat HIV known as protease inhibitors (ritonavir)

If you are going to have an operation where you will be given a general anaesthetic tell your doctor that you are taking Alprazolam.

### **Alprazolam with food and drink**

Do not drink alcohol whilst taking alprazolam; alcohol increases the effects of this medicine and therefore should be avoided.

### **Pregnancy and breast-feeding**

If you are pregnant or are planning to become pregnant, **do not** take alprazolam tablets unless you and your doctor have discussed the risks and benefits involved.

If alprazolam is taken regularly during the last 3 months of pregnancy, your baby might develop dependency to alprazolam and be at risk of suffering withdrawal symptoms following birth.

If your doctor has decided that you should receive this medicine during late pregnancy or during labour, your baby might suffer from low body temperature, floppiness, breathing and feeding difficulties.

### **Breast-feeding**

Do not take this medicine if you are breastfeeding since the drug may pass into the breast milk.

### **Children and adolescents**

Alprazolam is not recommended for children and adolescents under the age of 18 years.

### **Driving and using machines**

Do not drive or operate machinery after taking alprazolam because it can make you lose concentration or muscle control, feel dizzy, drowsy or light headed.

### **Important information about some of the ingredients of Alprazolam**

Alprazolam contains lactose. If you have been told, by your doctor that you have an intolerance to some sugars contact your doctor before taking alprazolam.

## **3. HOW TO TAKE ALPRAZOLAM**

### **Dosage**

Alprazolam tablets should be taken orally. Always take alprazolam exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Alprazolam should not be taken for longer than your doctor has advised and generally should not exceed 8-12 weeks.

### **Adults (Above the age 18 years)**

The usual dose is between 0.25 mg and 0.5 mg three times a day.

Your doctor may decide to increase your dose if necessary to a maximum of 3 mg a day. You should check with your doctor or pharmacist if you are not sure. Dosage increase should be made cautiously and the evening dose should be increased before the daytime dose.

A lower dose may be required if you have not previously received this type of medicine, or if you have a history of alcoholism.

If you have liver or kidney problems your doctor may start you on a lower dose than the above.

### **Elderly patients**

The usual dose for elderly patients is 0.25 mg two to three times a day. If physically fit your doctor may decide to increase the dose by 0.5 mg every three days to a maximum of 1.5 mg daily if necessary. Frail elderly patients should not exceed 0.75 mg a day.

### **If you take more Alprazolam than you should**

Contact your **doctor or local Accident and Emergency department immediately**. Take the container and any remaining tablets with you.

### **If you forget to take Alprazolam**

Do not take a double dose to make up for a missed dose, just take your next tablet when it is due.

### **If you stop taking Alprazolam**

Treatment with alprazolam should be gradually reduced before stopping. Your doctor will tell you how to do this. If treatment with alprazolam is interrupted or is stopped early you may suffer from side effects such as, anxiety or restlessness and you may have trouble sleeping. **Contact your doctor if you suffer from any of these symptoms and mood changes.**

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Alprazolam can cause side effects, although not everybody gets them.

Harmful or hostile behaviour has been seen in people with a history of violence, borderline personality disorders, history of alcohol abuse and people taking CNS medicine. If you suffer from post-traumatic stress disorder, stopping treatment with alprazolam can cause irritability, hostility and unpleasant ideas and thoughts.

Some common side effects observed at the start of therapy are drowsiness, sleepiness and unsteadiness (similar to feeling drunk), numbed emotions, loss of alertness or concentration, confusion, tiredness, headache, light-headedness, dizziness, muscle spasms or muscle weakness, jerky or uncoordinated movements, double or blurred vision, insomnia (inability to sleep or disturbed sleep), nervousness or feeling anxious, shakiness or trembling, loss of appetite or change in your weight. These generally disappear on continuation of treatment.

**Very Common side effects (affecting more than 1 in 10 people)**

- sleepiness or drowsiness

**Common side effects (affecting fewer than 1 in 10 people)**

- blurred vision
- constipation
- nausea
- confusion
- depression
- irritability
- decrease in appetite
- difficulty in controlling movements (ataxia)
- loss of coordination
- loss of strength
- difficulty remembering
- slurred speech
- lack of concentration
- dizziness
- headaches
- light-headedness

**Uncommon side effects (affecting fewer than 1 in 100 people)**

- high prolactin levels in the blood (hyperprolactinaemia)
- vomiting
- hallucinations
- rage
- hostile or aggressive behaviour
- anxiety
- agitation
- changes in your sex drive (men and women)
- difficulty sleeping
- abnormal thoughts
- nervousness
- feeling stimulated
- muscle weakness
- memory loss (amnesia)
- involuntary movements (dystonia)
- tremors
- sexual dysfunction
- irregular periods in women
- uncontrolled passing of urine (incontinence)
- difficulty urinating (urinary retention)
- inflammation of the skin (dermatitis)
- low blood pressure
- rapid heartbeat (tachycardia)
- diarrhoea
- increased saliva
- dry mouth
- abnormal liver function
- yellowing of skin or whites of eyes caused by liver problems (jaundice/ icterus)
- change in weight
- blocked nose
- skin reactions

- increase in intraocular pressure

#### **Rare side effects (affecting fewer than 1 in 1,000 people)**

- blood diseases (dyscrasia)

#### **Side effects occurring with unknown frequency**

- swelling due to excessive fluid in the body (peripheral oedema)
- swelling of the eyelids, face, lips, mouth tongue or throat which may cause difficulty in swallowing or breathing
- problems associated with the autonomic nervous system
- numbed emotions
- reduced alertness
- anorexia
- double vision
- fatigue
- hepatitis

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, **please tell your doctor or pharmacist.**

### **5. HOW TO STORE ALPRAZOLAM**

Keep out of the reach and sight of children.

Do not store above 25°C. Store in the original package.

**Do not use alprazolam after the expiry date, which is stated on the carton or bottle after EXP.**

The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

#### **What alprazolam contains**

- The active substance is alprazolam.
- The other ingredient(s) are lactose monohydrate, microcrystalline cellulose, maize starch, sodium benzoate, docusate sodium, polyvidone, colloidal silicon dioxide, sodium starch glycollate, magnesium stearate,
- The 0.5 mg tablets contain the colouring FD&C Blue #2 Aluminium Lake (E132) and erythrosine (E127).
- The 1.0 mg tablets contain the colouring FD&C Blue #2 Aluminium Lake (E132)

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

0.25 mg are white oval tablets and are marked "AL breakline 0.25" on one side and "G" on reverse.

0.5 mg are pink oval tablets and are marked "AL breakline 0.5" on one side and "G" on reverse.

1.0 mg are light blue oval tablets and are marked "AL breakline 1.0" on one side and "G" on reverse.

Alprazolam is available in containers of 20, 28, 30, 50, 56, 60, 84 and 100 and blisters of, 20, 28, 30, 40, 50, 56, 60, 84 and 100.

Not all pack sizes may be marketed.

## Marketing Authorisation Holder and Manufacturer

### Marketing Authorisation Holder

[To be completed Nationally]

### Manufacturer

McDermott Laboratories Ltd t/a Gerard Laboratories  
35/36 Baldoyle Industrial Estate  
Grange Road  
Dublin 13  
Ireland

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria	Alprazolam 'Arcana' 0.5mg Tabletten
Denmark	Alprazolam Mylan 0.25 mg Alprazolam Mylan 0.5 mg Alprazolam Mylan 1.0 mg
Finland	Alprazolam Mylan (0.25 mg, 0.5 mg and 1.0 mg)
Greece	Alprazolam/Generics TAB 0.25 mg/TAB Alprazolam/Generics TAB 0.5 mg/TAB Alprazolam/Generics TAB 1.0 mg/TAB
Italy	Alprazolam Mylan Generics (0.25 mg, 0.5 mg and 1.0 mg)
Luxembourg	Alprazolam Mylan Comprimés 0.25 mg Alprazolam Mylan Comprimés 0.5 mg Alprazolam Mylan Comprimés 1.0 mg
Netherlands	Alprazolam Mylan 0.25 mg Tabletten Alprazolam Mylan 0.5 mg Tabletten
Portugal	Alprazolam Mylan 0,25 mg Comprimidos Alprazolam Mylan 0,5 mg Comprimidos Alprazolam Mylan 1,0 mg Comprimidos
Spain	Alprazolam Mylan 0.25 mg Alprazolam Mylan 0.5 mg Alprazolam Mylan 1.0 mg

**This leaflet was last revised in {MM/YYYY}.**