Patient Information Leaflet

SCHEDULING STATUS

S5

MYLAN ALPRAZOLAM 0,25 mg (tablets)

MYLAN ALPRAZOLAM 0,5 mg (tablets)

MYLAN ALPRAZOLAM 1,0 mg (tablets)

Alprazolam

Lactose

Read all of this leaflet carefully before you are given MYLAN ALPRAZOLAM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- MYLAN ALPRAZOLAM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MYLAN ALPRAZOLAM is and what it is used for.

2. What you need to know before you are given MYLAN ALPRAZOLAM.

3. How to take MYLAN ALPRAZOLAM.

4. Possible side effects.

5. How to store MYLAN ALPRAZOLAM.

6. Contents of the pack and other information.

1. What MYLAN ALPRAZOLAM is and what it is used for

What MYLAN ALPRAZOLAM is:

- MYLAN ALPRAZOLAM belongs to a group of medicines known as benzodiazepines.

What it is used for:

- MYLAN ALPRAZOLAM is used for the treatment of anxiety disorders, or the short-term relief of symptoms of anxiety.
- It is also used for anxiety associated with depression and panic disorders.

2. What you need to know before you take MYLAN ALPRAZOLAM

MYLAN ALPRAZOLAM should not be taken:

- if you are pregnant, giving birth or breastfeeding;
- if you know that you are hypersensitive to the alprazolam or any of the ingredients in the MYLAN ALPRAZOLAM tablets or similar medicines;
- if you suffer from schizophrenia;
- if you are depressed and think of committing suicidal;
- if the treatment is for someone younger than 18 years old as excitement and irritability could occur in children. If the child is small, he or she may be more prone to these reactions;
- if you are taking ketoconazole , a medicine used to treat fungal infections.

Warnings and precautions

Special care should be taken with MYLAN ALPRAZOLAM:

- if you suffer from a psychotic illness, then MYLAN ALPRAZOLAM should not be used alone to treat your depression or anxiety with depression;

- you must be careful when taking MYLAN ALPRAZOLAM and you have a history of alcohol or substances abuse;
- if you want to stop taking MYLAN ALPRAZOLAM, speak to your doctor as you must gradually take less tablets until you can stop - do not stop suddenly as you may experience unpleasant withdrawal reactions;
- if you use MYLAN ALPRAZOLAM there is a possibility of dependency and if you suddenly stop taking the tablets you could have withdrawal symptoms. This may consist of headache, muscle pain, anxiety, tension, restlessness, confusion and irritability. If it is severe, contact your doctor;
- if you stop taking the MYLAN ALPRAZOLAM you may experience the same symptoms that you had before you started taking the tablets;
- if you take MYLAN ALPRAZOLAM the period of treatment should not be more than eight to twelve weeks in case of anxiety, including the tapering off period;
- if you suffer from kidney or liver disease – this may increase the chances of experiencing side effects with MYLAN ALPRAZOLAM;
- if you have a serious condition affecting your breathing;
- if you have epilepsy or a history of seizures – the risk of seizures may be increased when starting or suddenly stopping MYLAN ALPRAZOLAM treatment;
- if you suffer from depression unless there is some anxiety with the depression.

Children/ and adolescents

- When used in children under 18 years as these patients are more sensitive than adults to the effects of MYLAN ALPRAZOLAM. Reactions such as excitement and irritability may occur in children. Smaller children are more prone to these reactions.

Other medicines and MYLAN ALPRAZOLAM:

Always tell your healthcare professional if you are taking any other medicine. This includes complementary or traditional medicines.

- Imipramine and desipramine, medicines used to treat depression: MYLAN ALPRAZOLAM may increase the levels of these medicines in the body if taken together.
- Do not take MYLAN ALPRAZOLAM with ketoconazole, itraconazole or other azole antifugal medicines (used to treat fungal infections).
- It is recommended that the dose of MYLAN ALPRAZOLAM be decreased when given with nefazodone or fluvoxamine (medicines used to treat depression) or cimetidine (antacid medicine)– higher blood levels of MYLAN ALPRAZOLAM may occur and this can lead to more side effects. Your doctor may want to change the dose of MYLAN ALPRAZOLAM or give you a different medicine.
- Caution is recommended when MYLAN ALPRAZOLAM is given with any of the following medicines: fluoxetine (medicine used to treat depression), oral contraceptives (birth control pill), sertraline (medicine used to treat depression and panic attacks), diltiazem (medicine used to treat high blood pressure and chest pain) or macrolide antibiotics (e.g. erythromycin)
- Medicines used for sleeplessness and anxiety or other medicines used for panic attacks and stress reactions could increase the effect of MYLAN ALPRAZOLAM.
- If you drink alcohol it could increase the effect of MYLAN ALPRAZOLAM.

MYLAN ALPRAZOLAM with food and drink:

You may take MYLAN ALPRAZOLAM with food and drinks BUT NOT WITH ALCOHOL (*see sections 'Taking other medicines with MYLAN ALPRAZOLAM' and 'Special care should be taken with MYLAN ALPRAZOLAM ')*.

Pregnancy and breastfeeding and fertility:

- You should not take MYLAN ALPRAZOLAM during pregnancy
- You should not take MYLAN ALPRAZOLAM during labour.
- You should not take MYLAN ALPRAZOLAM when you are breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking MYLAN ALPRAZOLAM.

Driving and using machinery:

It is not always possible to predict to what extent MYLAN ALPRAZOLAM may interfere with the daily activities of a patient. MYLAN ALPRAZOLAM can cause dizziness and drowsiness.

Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MYLAN ALPRAZOLAM affects them.

MYLAN ALPRAZOLAM contains lactose and sodium benzoate:

MYLAN ALPRAZOLAM contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose intolerance should not take MYLAN ALPRAZOLAM.

Sodium Benzoate – this medicine contains 0.10 mg Sodium Benzoate in each tablet.

4. HOW TO TAKE MYLAN ALPRAZOLAM

- Do not share medicines prescribed for you with any other person.
- Always take MYLAN ALPRAZOLAM exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Your doctor will tell you how long your treatment with MYLAN ALPRAZOLAM will last.
- If you have the impression that the effect of MYLAN ALPRAZOLAM is too strong or too weak, tell your doctor or pharmacist.

The usual dose is:

For anxiety:

The usual starting dose is 0,25 mg to 0,5 mg taken three times a day. Your doctor may increase your dose if needed. However, the dose usually is not more than 4 mg a day.

For mixed anxiety/depression:

The usual starting dose is 0,5 mg taken three times a day. Your doctor may increase your dose if needed. However, the dose usually is not more than 4,5 mg a day.

For panic disorders:

The usual starting dose is 0,5 mg to 1,0 mg given at bedtime or 0,5 mg taken three times a day. Your doctor may increase your dose if needed. However, the dose usually is not more than 10 mg a day.

For elderly patients:

The usual starting dose is 0,25 mg taken two or three times a day. Your doctor may increase your dose if needed. However, the dose usually is not more than 0,75 mg a day.

If you take more MYLAN ALPRAZOLAM than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. These are the

possible signs and symptoms of overdosage: slurred speech or confusion, severe drowsiness, staggering or walking unsteadily, difficulty breathing or coma.

If you missed a dose of MYLAN ALPRAZOLAM

Do not take a double dose to make up for forgotten individual doses.

If you stop taking MYLAN ALPRAZOLAM

Do not stop treatment early because the quantity of tablets that you are taking must be reduced gradually to avoid getting withdrawal symptoms (*see 'Take special care with MYLAN ALPRAZOLAM*').

4. POSSIBLE SIDE EFFECTS

Not all side effects reported for MYLAN ALPRAZOLAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using MYLAN ALPRAZOLAM, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking MYLAN ALPRAZOLAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MYLAN ALPRAZOLAM. You may need urgent medical attention or

hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Blurred vision (not seeing clearly),

peripheral oedema (swelling of hands and feet due to the retained fluids),

angioedema (swelling beneath the skin),

aggressive behaviour,

hallucinations (seeing, hearing or feeling things that are not there),

rage (uncontrolled anger).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

Anorexia (lack or loss of appetite for food),

confusion (more common in the elderly),

depression,

irritability,

changes in sexual desire,

dizziness,

headache,

lack of memory,

constipation,

nausea,

feeling tired,

dry mouth.

The following side effects have been reported less frequently:

Insomnia (inability to sleep),

mood changes,

nervousness,

amnesia (lack of memory),

tremor (shakiness),

diarrhoea,

vomiting,

muscle twitching or weakness,

changes in menstrual period,

changes in weight.

agitation,

slurred speech.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/. By reporting side effects, you can help provide more information on the safety of MYLAN ALPRAZOLAM.

5. How to store MYLAN ALPRAZOLAM

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Store in the original package / container.
- Keep the container tightly closed.
- Protect from light.
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MYLAN ALPRAZOLAM contains:

- The active substance is alprazolam.

  Each tablet contains 0,25 mg, 0,5 mg, or 1,0 mg alprazolam.
- The other ingredients in tablet 0,25 mg**:** Colloidal silica anhydrous, docusate sodium, magnesium stearate, maize starch, microcrystalline cellulose 101, povidone K 30, sodium starch glycollate, lactose
- The other ingredients in tablet 0,5 mg**:** Colloidal silica anhydrous, docusate sodium, magnesium stearate, maize starch, microcrystalline cellulose 101, povidone K 30, sodium starch glycollate {colourants: FD&C Blue No 2 CI 73015, Erythrosine Al Lake CI 45430}, lactose
- The other ingredients in tablet 1 mg**:** Colloidal silica anhydrous, docusate sodium, magnesium stearate, maize starch, microcrystalline cellulose, povidone K 30, sodium starch glycollate {colourant: FD&C Blue No 2 (Al Lake)}, lactose

- Preservative: Sodium benzoate
- Contains sugar (lactose)

What MYLAN ALPRAZOLAM looks like and contents of the pack

What MYLAN ALPRAZOLAM looks like:

MYLAN ALPRAZOLAM 0,25 mg tablets are white, ovoid shaped 9 mm by 5,5 mm

MYLAN ALPRAZOLAM 0,5 mg tablets are pink, ovoid shaped 9 mm by 5,5 mm

MYLAN ALPRAZOLAM 1,0 mg tablets are lavender, ovoid shaped 9 mm by 5,5 mm

Contents of the pack:

White HDPE bottles of 50 tablets or white polypropylene containers containing 30, 50, 100 or 300 tablets.

Holder of Certificate of Registration and Manufacture

Viatris Healthcare (Pty) Ltd

4 Brewery Street,

Isando, Gauteng,

1601

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Registration number

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MYLAN ALPRAZOLAM 0,5 mg, tablets: 32/2.6/0373

MYLAN ALPRAZOLAM 1,0 mg, tablets: 32/2.6/0323

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website