PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

BIOZANE 0,25 tablets

Alprazolam

BIOZANE contains sugar

BIOZANE 0,25 contains 100,0 mg lactose monohydrate per tablet

Read all of this leaflet carefully before you start taking BIOZANE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- BIOZANE 0,25 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 BIOZANE 0,25 is and what it is used for
2. What you need to know before you take BIOZANE 0,25
3. How to take BIOZANE 0,25
4. Possible side effects
5. How to store BIOZANE 0,25

6. Contents of the pack and other information

1. What BIOZANE 0,25 is and what it is used for

BIOZANE 0,25 is a tranquilliser containing the active ingredient alprazolam. Alprazolam belongs to a group of medicines called benzodiazepines. Benzodiazepines affect chemical activity in the brain to promote sleep and reduce anxiety and worry.

BIOZANE 0,25 tablets are used for the short-term relief of symptoms of anxiety. It is also used in the treatment of anxiety disorders, anxiety associated with depression, depression, and panic disorders.

2. What you need to know before you take BIOZANE 0,25

Do not take BIOZANE 0,25:

- if you are hypersensitive (allergic) to alprazolam or other similar benzodiazepine medicines or any of the other ingredients of BIOZANE 0,25 (listed in section 6)
- if you are pregnant, in labour or if you are breastfeeding
- if you suffer from a disease called ‘myasthenia gravis’ where you suffer from very weak and tired muscles
- if you suffer from severe chest problems or breathing difficulties
- if you suffer from an eye condition called ‘acute narrow angle glaucoma’
- if you are psychotic, suffer from mental depression or if you have thoughts of taking your own life
- if you suffer from a condition called “sleep apnoea” – your breathing stops and starts while you sleep
- if you are in a coma or suffer from acute lung problems
- if you suffer from severe liver problems
- if you suffer from a condition called schizophrenia
- if you are younger than 18 years

- if you are taking antiretroviral protease inhibitors medication used in the treatment of HIV, ketoconazole, itraconazole or similar medicine to treat fungal infections

Warnings and precautions

Special care should be taken with BIOZANE 0,25:

- if you suffer from certain types of depression
- you should not take BIOZANE if you are psychotic or suffer from mental depression unless you are very anxious.
- if you suffer from panic disorders associated with a certain type of depression taking BIOZANE may expose suicidal thoughts or plans.
- if you have problems with your lungs, kidneys or liver.
- there is a potential for developing dependence (addiction) if you take BIOZANE 0,25 for long periods or if you take high doses. The risk for getting addicted to BIOZANE 0,25 is also greater if you have abused drugs or alcohol in the past.

  If addicted to BIOZANE 0,25 and you try to stop using it too quickly, withdrawal symptoms such as headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability may be experienced.
- in severe cases the following symptoms may occur: a mental state where you feel detached from your surroundings, everyday sounds seem much louder than they should, numbness or tingling of the hands and feet, hypersensitivity to light, noise and physical contact, hallucinations or epileptic seizures.
- withdrawal symptoms may occur if BIOZANE 0,25 is suddenly stopped. Therapy should be gradually reduced.

- withdrawal symptoms include the following: generalised unhappiness, sleeplessness, abdominal and muscle cramps, vomiting, sweating, shakiness and sudden and involuntary muscle contractions (convulsions).
- if you suffer from epilepsy, BIOZANE 0,25 can cause seizures. Seizures can also occur if you suddenly stop BIOZANE 0,25.
- if you stop BIOZANE 0,25 too quickly, there is a risk that the symptoms that has led to the treatment of BIOZANE 0,25 may reoccur in an enhanced form. It is therefore recommended that the dosage is decreased gradually.
- if you have a history of alcohol or drug abuse, BIOZANE 0,25 should be used with extreme caution.
- the duration of taking BIOZANE 0,25 should be as short as possible. If it is taken for anxiety, it should not be used longer than eight to twelve weeks, including the tapering off process.
- if BIOZANE 0,25 is taken by the elderly and debilitated patients they should be very careful monitored for side-effect such as sleepiness and muscle weakness which might cause these patients to fall and obtain serious injuries.
- Reactions like
- taking BIOZANE 0,25 together with pain medication containing a certain type of ingredient called opioids can cause sleepiness, ineffective breathing, coma and death. If it can not be avoided to take these two types of medication together, the lowest effective dose of the pain medication should be used and the duration of the treatment should be as short as possible.
- taking benzodiazepines such as BIOZANE 0,25 can cause a decreased ability to remember new information which may result in limited or total inability to remember events and it is therefore necessary to have uninterrupted sleep of 7-8 hours after taking this medication.
- if you go through a period of grief, the necessary psychological adjustment may not be accomplished

- if you use BIOZANE 0,25 for prolonged periods, the effectiveness to the hypnotic effects may be decreased.
- if you take other central nervous system depressant agents the side-effects such as sleepiness, ineffective breathing and slow heart function may be enhanced.
- if the wall of your arteries in your brain is thickened and hardened (arteriosclerosis) BIOZANE 0,25 should be used with caution.

Children

Do not give BIOZANE 0,25 to children under the age of 18 years because it is unlikely to be safe.

Other medicines and BIOZANE 0,25

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- Antidepressant medicine e.g., imipramine and desimipramine, fluoxetine, sertraline
- Pain medication than contains opioids
- Sedative medicines such as other benzodiazepines
- Alcohol and other central nervous system depressants
- Reduce the dose of BIOZANE 0,25 if you are taking medication such as fluvoxamine (to treat depression) and cimetidine (to treat stomach ulcers).
- Oral contraceptives
- Diltiazem (blood pressure medicine)
- Antibiotic such as erythromycin
- Antifungal medicine (ketoconazole, itraconazole)
- HIV medicine (e.g., ritonavir)
- Digoxin (used to treat heart conditions)

BIOZANE 0,25 with alcohol

It is important not to drink any alcohol while you are taking BIOZANE 0,25 as alcohol increases the effects of the medicine.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

It is not always possible to predict to what extent BIOZANE 0,25 may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which BIOZANE 0,25 affects you.

BIOZANE 0,25 may cause drowsiness or dizziness.

Patients receiving BIOZANE 0,25 should be advised not to operate motor vehicles or dangerous machinery or climb dangerous heights until it is established that they do not became drowsy or dizzy while receiving BIOZANE 0,25. In these situations, impaired decision making could lead to accidents.

BIOZANE 0,25 contains lactose

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

3. How to take BIOZANE 0,25

Do not share medicines prescribed for you with any other person.

Always take BIOZANE 0,25 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of BIOZANE 0,25 varies from one person to another. In patients who require higher doses, your doctor will choose the right dose for you.

A. **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, given in divided doses.

B. **For mixed anxiety/depression - anxiety associated with 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 given in divided doses.

C. **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.

D. **For elderly patients or in the presence of debilitating disease:**

   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.

Your doctor will tell you how long your treatment with BIOZANE 0,25 will last. Do not stop treatment early because withdrawal symptoms may occur following rapid decrease or abrupt discontinuation of BIOZANE 0,25. Dosage should be reduced slowly. If you have the impression that the effect of is too strong or too weak, tell your doctor or pharmacist

If you take more BIOZANE 0,25 than you should

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

If you forget to take BIOZANE 0,25

If you forgot to take a dose, take it as soon as you remember. Then take any remaining doses for that day at regular spaced intervals. Do not take a double dose to make up for forgotten individual doses.

If you stop taking BIOZANE 0,25

Do not stop treatment early because withdrawal symptoms may occur following rapid decrease or abrupt discontinuation of BIOZANE 0,25. Dosage should be reduced slowly.

4. Possible side effects

BIOZANE 0,25 can have side effects.

Not all side effects reported for BIOZANE 0,25 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIOZANE 0,25 please consult your health care provider for advice.

Some side effects of BIOZANE 0,25 include the following:

Frequent:

- lack or loss of appetite
- confusion, depression, irritability, anxiety, loss of memory, difficulty in paying attention, nervousness
- changes in sexual desire
- sleep disorders such as excessive sleeping or inability to sleep, feeling tired, lack of energy
- dizziness, impaired balance, loss of control of full bodily movements (ataxia), shakiness
- headache

- unclear pronouncing of words (dysarthria)
- blurred vision (not seeing clearly)
- nausea, constipation, dry mouth

Less frequent:

- feeling annoyed, aggression. mood disorder, hallucinations, violent behaviour, disinhibition, sleep disturbance, abnormal thinking
- change in sexual desire; sexual dysfunction
- slurred speech
- memory loss
- visual disturbances, high pressure in the eye
- sensation of whirling and loss of balance (vertigo), muscle twitching or weakness
- imbalance, movement disorder in which your muscles contract involuntarily (dystonia)
- low blood pressure
- breathing difficulty
- changes in salivation, diarrhoea and vomiting
- abnormal liver function: liver disease that cause yellowing of the skin and whites of the eyes
- skin irritation, swelling underneath the skin, swelling of lower legs or hand; photosensitivity reaction (extreme sensitivity to UV rays from the sun)
- changes in urinary frequencies, unable to empty bladder completely
- changes in menstrual period, irregular menstruation
- changes in weight
- higher-than-normal prolactin in your blood

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. 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/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of BIOZANE 0,25.

5. How to store BIOZANE 0,25

Store all medicines out of reach of children.

Store at 25ºC.

6. Contents of the pack and other information

What BIOZANE 0,25 contains

- The active substance is 0,25 mg alprazolam in one 0,25 mg tablet
- The other ingredients are lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate

What BIOZANE 0,25 looks like and contents of the pack

BIOZANE 0,25 mg tablets are white oval, biconvex, scored tablets and plain on one side

BIOZANE 0,25 is available in white, polyethylene (HDPE) bottles containing 100 and 1 000 tablets.

BIOZANE 0,25 is available in ALU foil blisters containing 10 tablets in cartons of 30 or 100 tablets.

Holder of Certificate of Registration

Biotech Laboratories (Pty) Ltd

Ground Floor, Bock K,

400, 16th Road, Halfway House

Randjiespark

1685

Tel: +27 (11) 848 3050

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Access to the corresponding Professional Information

TBA