

Applicant: **Biotech Laboratories (Pty) Ltd**
Product Name: Biozane 0,5 mg & 1 mg (28/2.6/0001/2)
Dosage form: Tablets
Strength: Each tablet contains 0,5 or 1,0 mg alprazolam respectively

1.3.2 Approved Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

BIOZANE 0,5 mg tablets

BIOZANE 1 mg tablets

Alprazolam

BIOZANE contains sugar.

BIOZANE 0,5 mg contains 90,0 mg lactose per tablet.

BIOZANE 1 mg contains 180,0 mg lactose 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 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 is and what it is used for
2. What you need to know before you take BIOZANE
3. How to take BIOZANE
4. Possible side effects
5. How to store BIOZANE
6. Contents of the pack and other information

1. What BIOZANE is and what it is used for

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BIOZANE 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 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

Do not take BIOZANE:

- if you are hypersensitive (allergic) to alprazolam or other similar benzodiazepine medicines or any of the other ingredients of BIOZANE (listed in section 6)
- if you suffer from a condition called schizophrenia
- if you are taking antiretroviral protease inhibitors used in the treatment of HIV and medication such as ketoconazole, itraconazole or similar medicine to treat fungal infections
- If you are below the age of 18 years
- 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 sleep apnoea - your breathing stops and starts while you sleep
- if you suffer from severe liver problems

Warnings and precautions

Special care should be taken with BIOZANE:

- if you suffer from certain types of depression.
- if you have abused drugs or alcohol in the past, or find it difficult to stop taking medicines, drinking alcohol or taking drugs.
- when stopping BIOZANE too quickly or abruptly – you may experience withdrawal symptoms like inability to sleep, stomach or muscle cramps, vomiting, sweating, convulsions/seizures.

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- if you stop BIOZANE too quickly, there is a risk that the symptoms that has led to the treatment of BIOZANE may reoccur in an enhanced form. It is therefore recommended that the dosage is decreased gradually.
- the duration of using BIOZANE 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 you have problems with your lungs, kidneys or liver.
- you should not take BIOZANE if you are psychotic or suffer from mental depression unless you are very anxious.
- elderly and debilitated patients should be very careful when taking BIOZANE as they are at increased risks of sleepiness, breathing difficulties and the loss of control of bodily movements.
- if you suffer from panic disorders associated with a certain type of depression taking BIOZANE may expose suicidal thoughts or plans.
- taking BIOZANE together with pain medication containing a certain type of ingredient called opioids can cause sleepiness, ineffective breathing, coma and death. If it cannot 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 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 take benzodiazepines such as BIOZANE, psychiatric reactions and reactions such as, restlessness, irritability, aggressiveness, hallucinations and inappropriate behaviour may occur. This is more like to occur in children and elderly patients. Should this occur, the use of BIOZANE should be stopped.

Children

Do not give BIOZANE to children under the age of 18 years.

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Other medicines and BIOZANE

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

- Alcohol and other central nervous system depressants
- Antidepressant medicine e.g., imipramine and desimipramine, fluoxetine, sertraline
- Reduce the dose of BIOZANE 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
- Pain medication than contains opioids
- Antifungal medicine (ketoconazole, itraconazole)
- HIV medicine (e.g., ritonavir)
- Digoxin (used to treat heart conditions)

BIOZANE with alcohol

It is important not to drink any alcohol while you are taking BIOZANE, 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 healthcare provider for advice before taking this medicine.

Do not take BIOZANE if you are pregnant or breastfeeding your baby.

Driving and using machines

It is not always possible to predict to what extent BIOZANE may interfere with your daily activities. You should

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ensure that you do not engage in driving or operating machinery until you are aware of the measure to which BIOZANE affects you.

BIOZANE may cause drowsiness or dizziness.

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

BIOZANE 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

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

Always take BIOZANE 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 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 4,0 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 10,0 mg a day.

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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 will last. Do not stop treatment early because withdrawal symptoms may occur following rapid decrease or abrupt discontinuation of BIOZANE. 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 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

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

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

4. Possible side effects

BIOZANE can have side effects.

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

Tell your doctor if you notice any of the following:

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Frequent:

- Lack or loss of appetite
- Confusion, depression, irritability, disorientation, anxiety
- Changes in sexual desire
- Feeling tired, excessive sleeping
- Dizziness, impaired balance, loss of control of full bodily movements (ataxia)
- Headache
- Loss of memory
- Unclear pronouncing of words (dysarthria)
- Lack of energy
- Difficulty in paying attention
- Blurred vision (not seeing clearly)
- Nausea, constipation
- Dry mouth

Less frequent:

- Aggressive behaviour, inability to sleep, mood changes, nervousness, hallucinations, irritability, anger
- Lack of memory, shakiness, slurred speech, concentration difficulties
- Eye pain
- Diarrhoea and vomiting
- Abnormal liver function
- Skin irritation
- Muscle twitching or weakness
- Changes in urinary frequencies
- Changes in menstrual period, sexual dysfunction
- Changes in weight

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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.

5. How to store BIOZANE

Store all medicines out of reach of children.

Store below 25 °C.

Protect from moisture and light.

6. Contents of the pack and other information

What BIOZANE contains

- The active substance is alprazolam.
- The other ingredients are lactose, maize starch, gelatine, magnesium stearate.

What BIOZANE looks like and contents of the pack

BIOZANE 0,5 mg tablets are white to almost white, flat, round tablets (diameter 7 mm).

BIOZANE 1 mg tablets are white to almost white, flat, round tablets (diameter 9 mm).

Glass container

Brown, amber glass container closed with a pilfer-proof closure lined with expanded polyethylene, aluminium and polyester film.

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Pack size: 30 or 100 tablets.

Blister pack

Transparent PVC/PVDC and silver Alu blister strips; 10 tablets per blisters strip. Pack size: 30 or 100 tablets.

HPDE container

A 60 cc or 100cc white, opaque HDPE container with white Opaque Polypropylene Fine ribbed 33mm screw cap with induction sealing wad.

Pack size: 30 or 100 tablets.

Holder of Certificate of Registration

Biotech Laboratories (Pty) Ltd

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This leaflet was last revised in

30 April 2024

Registration number

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Access to the corresponding Professional Information

TBA