

BIOZANE

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

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.
- 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.

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 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.

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:

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 disfunction
- Changes in weight

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.

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

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Registration number

BIOZANE 0,5 mg: 28/2.6/0001
BIOZANE 1 mg: 28/2.6/0002

BIOZANE

PASIËNT INLIGTINGSPAMFLET

SKEDULERING STATUS:

[55]

BIOZANE 0,5 mg tablette
BIOZANE 1 mg tablette
Alprasolam
BIOZANE bevat suiker
BIOZANE 0,5 mg bevat 90,0 mg laktose per tablet.
BIOZANE 1 mg bevat 180,0 mg laktose per tablet.

Lees die hele pamflet noukeurig deur voordat jy BIOZANE begin neem

- Bewaar hierdie pamflet. Jy sal dit dalk weer moet lees.
- Indien u verdere vrae het, vra asseblief jou dokter of apteker.
- BIOZANE is persoonlik vir jou voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al is hul simptome dieselfde as joune.

Wat hierdie pamflet bevat:

1. Wat BIOZANE is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy BIOZANE neem
3. Hoe om BIOZANE te neem
4. Moontlike newe-effekte
5. Hoe om BIOZANE te berg
6. Inhoud van die pakkie en ander inligting

1. Wat BIOZANE is en waarvoor dit gebruik word

BIOZANE is 'n kalmeermiddel wat die aktiewe bestanddeel alprasolam bevat. Alprasolam behoort aan 'n groep medisyne wat bensodiasiepiene genoem word. Bensodiasiepiene beïnvloed chemiese aktiwiteit in die brein om slaap te bevorder en angs en bekommernis te verminder. BIOZANE tablette word gebruik vir die korttermyn verligting van simptome van angs. Dit word ook gebruik in die behandeling van angsversteurings, angs wat verband hou met depressie, depressie en paniekversteurings.

2. Wat jy moet weet voordat jy BIOZANE neem

Moenie BIOZANE neem:

- as jy hipersensitief (allergies) is vir alprasolam of ander soortgelyke bensodiasiepienmedisyne of enige van die ander bestanddele van BIOZANE (gelys in afdeling 6)
- as jy aan 'n toestand genaamd skisofrenie ly
- as jy antiretrovirale protease-inhibeerders gebruik wat gebruik word in die behandeling van MIV en medikasie soos ketokonasool, itrakonasool of soortgelyke medisyne om swaminfeksies te behandel
- as jy onder die ouderdom van 18 jaar is
- as jy aan 'n siekte genaamd 'myasthenia gravis' ly waar jy aan baie swak en moeë spiere ly.
- as jy aan ernstige borsprobleme of asemhalingsprobleme ly
- as jy aan slaapapnee ly – jou asemhaling stop en begin terwyl jy slaap
- as jy aan ernstige lewerprobleme ly

Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet geneem word met BIOZANE:

- as jy aan sekere tipes depressie ly.
- as jy dwelms of alkohol in die verlede misbruik het, of dit moeilik vind om op te hou om medisyne te neem, alkohol te drink of dwelms te gebruik.
- wanneer BIOZANE te vinnig of skielik gestaak word – jy mag onttrekkingsimptome ervaar soos onvermoë om te slaap, maag- of spierkrampe, braking, sweet, stuiptrekkings/stuipe.
- as jy BIOZANE te vinnig stop, is daar 'n risiko dat die simptome wat tot die behandeling van BIOZANE gelei het weer in 'n versterkte vorm kan voorkom. Dit word dus aan beveel dat die dosis geleidelik verlaag word.
- die duur van die gebruik van BIOZANE moet so kort as moontlik wees. As dit vir angs geneem word, moet dit nie langer as agt tot twaalf weke gebruik word nie, insluitend die aftrapproses.
- as jy probleme met jou longe, niere of lewer het.
- jy moet nie BIOZANE neem as jy psigoties is of aan geestelike depressie ly nie, tensy jy baie angstig is.
- bejaarde en verswakte pasiënte moet baie versigtig wees wanneer hulle BIOZANE neem, aangesien hulle 'n groter risiko loop van slaperigheid, asemhalingsprobleme en die verlies van beheer oor liggaamsbewegings.
- as jy aan paniekversteurings ly wat verband hou met 'n sekere tipe depressie, kan die gebruik van BIOZANE selfmoordgedagtes of -planne blootstel.
- die neem van BIOZANE saam met pynmedikasie wat 'n sekere soort bestanddeel genaamd opioïede bevat, kan slaperigheid, oneffektiewe asemhaling, koma en dood veroorsaak. As dit nie vermy kan word om hierdie twee tipes medikasie saam te neem nie, moet die laagste effektiwiese dosis van die pynmedikasie gebruik word en die duur van die behandeling moet so kort as moontlik wees.
- die gebruik van bensodiasiepiene soos BIOZANE kan 'n verminderde vermoë om nuwe inligting te onthou veroorsaak wat kan lei tot beperkte of totale onvermoë om gebeurtenisse te onthou en dit is dus nodig om ononderbroke slaap van 7-8 uur te hê nadat hierdie medikasie geneem is.
- as jy bensodiasiepiene soos BIOZANE neem, kan psigiatriese reaksies en reaksies soos rusteloosheid, prikkelbaarheid, aggressiwiteit, hallusinasies en onvanpaste gedrag voorkom. Dit kom meer voor by kinders en bejaarde pasiënte. Indien dit voorkom, moet die gebruik van BIOZANE gestaak word.

Kinders

Moenie BIOZANE aan kinders onder die ouderdom van 18 jaar gee nie.

Ander medisyne en BIOZANE

Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)

- Alkohol en ander sentrale senuweestelsel-depressante
- Antidepressante medisyne, bv. imipramien en desimiprami en, fluoksetien, sertralien
- Verminder die dosis BIOZANE as jy medikasie soos fluvoksamien (om depressie te behandel) en simetidien (om maagsere te behandel) neem.
- Orale voorbehoedmiddels
- Diltiasiem (bloeddrukmedisyne)
- Antibiotikum soos eritromisien
- Pynmedikasie wat opioïede bevat
- Antifungale medisyne (ketokonasool, itrakonasool)
- MIV-medisyne (bv. ritonavir)
- Digoksien (gebruik om harttoestande te behandel)

BIOZANE met alkohol

Dit is belangrik om geen alkohol te drink terwyl jy BIOZANE neem nie, aangesien alkohol die effek van die medisyne verhoog.

Swangerskap en borsvoeding

As jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne gebruik. Moenie BIOZANE neem as jy swanger is of jou baba borsvoed nie.

Bestuur en gebruik van masjiene

Dit is nie altyd moontlik om te voorspel tot watter mate BIOZANE met jou daaglikse aktiwiteite kan inmeng nie. U moet verseker dat u nie bestuur of masjinerie bestuur nie totdat u bewus is van die mate waarin BIOZANE u beïnvloed. BIOZANE kan lomerigheid of duiseligheid veroorsaak. Pasiënte wat BIOZANE ontvang, moet aangeraai word om nie motorvoertuie of gevaarlike masjinerie te bestuur of gevaarlike hoogtes te klim totdat vasgestel is dat hulle nie lomerig of duiselig geword het terwyl hulle BIOZANE gebruik nie. In hierdie situasies kan verswakte besluitneming tot ongelukke lei.

BIOZANE bevat laktose

Pasiënte met seldsame oorerflike probleme van galaktose-intoleransie, die Lapp-laktasetekort of glukose-galaktose-wanabsorpsie moet nie hierdie medisyne gebruik nie.

3. Hoe om BIOZANE te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem BIOZANE altyd presies soos jou dokter of apteker vir jou gesê het. Praat met jou dokter of apteker as jy nie seker is nie. Die gewone dosis BIOZANE verskil van persoon tot persoon. By pasiënte wat hoër dosisse benodig, sal jou dokter die regte dosis vir jou kies.

A. Vir angs:

Die gewone aanvangsdosis is 0,25 mg tot 0,5 mg wat drie keer per dag geneem word. Jou dokter kan jou dosis verhoog indien nodig. Die dosis is egter gewoonlik nie meer as 4,0 mg per dag nie, gegee in verdeelde dosisse.

B. Vir gemengde angs/depressie - angs wat met depressie geassosieer word:

Die gewone aanvangsdosis is 0,5 mg drie keer per dag geneem. Jou dokter kan jou dosis verhoog indien nodig. Die dosis is egter gewoonlik nie meer as 4,5 mg per dag gegee in verdeelde dosisse nie.

C. Vir paniekversteurings:

Die gewone aanvangsdosis is 0,5 mg tot 1,0 mg gegee voor slaaptyd of 0,5 mg drie keer per dag geneem. Jou dokter kan jou dosis verhoog indien nodig. Die dosis is egter gewoonlik nie meer as 10,0 mg per dag nie.

D. Vir bejaarde pasiënte of in die teenwoordigheid van aftakelende siekte:

Die gewone aanvangsdosis is 0,25 mg wat twee of drie keer per dag geneem word. Jou dokter kan jou dosis verhoog indien nodig. Die dosis is egter gewoonlik nie meer as 0,75 mg per dag nie.

Jou dokter sal jou vertel hoe lank jou behandeling met BIOZANE sal duur. Moenie behandeling vroeg staak nie, want onttrekkingsimptome kan voorkom na 'n vinnige afname of skielike staking van BIOZANE. Dosis moet stadig verminder word. As jy die indruk het dat die effek van te sterk of te swak is, vertel jou dokter of apteker

As jy meer BIOZANE neem as wat jy moet

In die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As jy vergeet om BIOZANE te neem

As jy vergeet het om 'n dosis te neem, neem dit so gou as wat jy onthou. Neem dan enige oorblywende dosisse vir daardie dag met gereelde tussenposes. Moenie 'n dubbeldosis neem om vergete individuele dosisse in te haal nie.

As jy ophou om BIOZANE te neem

Moenie behandeling vroeg staak nie, want onttrekking-simptome kan voorkom na 'n vinnige afname of skielike staking van BIOZANE. Dosis moet stadig verminder word.

4. Moontlike newe-effekte

BIOZANE kan newe-effekte hê. Nie alle newe-effekte wat vir BIOZANE aangemeld is, is in hierdie pamflet ingesluit nie. Indien jou algemene gesondheid versleg of as jy enige nadelige effekte ervaar terwyl jy BIOZANE neem, raadpleeg asseblief jou gesondheidsorgver-skaffer vir advies.

Vertel jou dokter as jy enige van die volgende opmerk:

Gereelde:

- Gebrek aan of verlies aan eetlus
- Verwarring, depressie, prikkelbaarheid, disoriëntasie, angs
- Veranderinge in seksuele begeerte
- Voel moeg, oormatige slaap
- Duiseligheid, verswakte balans, verlies van beheer oor volle liggaamlike bewegings (ataksie)
- Hoofpyn
- Verlies aan geheue
- Onduidelike uitspraak van woorde (disartrie)
- Gebrek aan energie
- Moeilikheid om aandag te gee
- Dowwe visie (sien nie duidelik nie)
- Naarheid, hardlywigheid
- Droë mond

Minder gereeld:

- Aggressiewe gedrag, onvermoë om te slaap, gemoedsveranderinge, senuweeagtigheid, hallusinasies, prikkelbaarheid, woede
 - Gebrek aan geheue, beweerigheid, onduidelike spraak, konsentrasieprobleme
 - Oogpyn
 - Diarree en braking
 - Abnormale lewerfunksie
 - Velirritasie
 - Spiertrekkings of swakheid
 - Veranderinge in urinêre frekwensies
 - Veranderinge in menstruasieperiode, seksuele disfunksie
 - Veranderinge in gewig
- Indien u enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte

As jy newe-effekte kry, praat met jou dokter of, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA rapporteer via die “**6.04 Adverse Drug Reaction Reporting Form**”, wat aanlyn gevind word onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van BIOZANE te verskaf.

5. Hoe om BIOZANE te bewaar

Berg alle medisyne buite bereik van kinders. Berg by of benede 25 °C. Beskerm teen vog en lig.

6. Inhoud van die pakkie en ander inligting

Wat BIOZANE bevat:

- Die aktiewe bestanddeel is alprasolam.
- Die ander bestanddele is laktose, mieliestysel, gelatien, magnesiumstearaat.

Hoe lyk BIOZANE en inhoud van die verpakking

BIOZANE 0,5 mg tablette is wit tot amper wit, plat, ronde tablette (deursnee 7 mm).
BIOZANE 1 mg tablette is wit tot amper wit, plat, ronde tablette (deursnee 9 mm).

Glashouer

Bruin, amberkleurige glashouer toegemaak met 'n diefwerende sluiting wat met uitgebreide poliëteen-, aluminium- en poliësterfilm uitgevoer is.

Verpakkingsgrootte: 30 of 100 tablette.

Blisterverpakking

Deursigtige PVC/PVDC en silwer Alu blisterstroke; 10 tablette per blisterstrook. Verpakkingsgrootte: 30 of 100 tablette.

HPDE houer

'n 60 cc of 100 cc wit, ondeursigtige HDPE-houer met wit Ondeursigtige Polipropileen Fyn geribde 33 mm skroefdrop met induksie verseëling. Verpakkingsgrootte: 30 of 100 tablette.

Houer van Registrasiesertifikaat

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Hierdie pamflet is laas hersien

10 Mei 2024

Registrasiensommer

BIOZANE 0,5 mg: 28/2,6/0001
BIOZANE 1 mg: 28/2,6/0002