BIOZANE 0,25

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:
S5

BIOZANE 0,25 tablets
Alprazolam
BIOZANE 0,25 contains sugar
BIOZANE 0,25 contains 100,0 mg lactose monohydrate per tablet

Read all of this leaflet carefully before you start taking BIOZANE 0,25
- 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 (as the use of BIOZANE 0,25 has not been established)
- you should not take BIOZANE 0,25 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 0,25 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 you use BIOZANE 0,25 for prolonged periods, the effectiveness to the hypnotic effects may be decreased.
- 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 restlessness, agitation, irritability, aggressiveness, delusions, rages, nightmares, hallucinations, inappropriate behavior and other adverse behavioral effects are known to occur when using benzodiazepines. These reactions are more likely to occur in children and the elderly. If this occur, the use of BIOZANE 0,25 should be stopped.
- 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 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 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.
- taking BIOZANE 0,25 may lead to episodes of mental illness marked by periods of feeling intense excitement and happiness, delusions and overactivity.
- 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 healthcare 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 healthcare 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 taking 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 monohydrate
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 4,0 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 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 healthcare 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, sexual dysfunction
- 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)
- skin irritation
- 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
- 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

Frequency unknown:
- abnormal thinking, aggression, mood disorders
- gastrointestinal disorder
- imbalance, movement disorder in which your muscles contract involuntarily (dystonia)
- abnormal liver function
- swelling underneath the skin, swelling of lower legs or hand; photo sensitivity reaction (extreme sensitivity to UV rays from the sun)
- unable to empty bladder completely
- high pressure in the eye

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 below 25 °C.

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.

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Access to the corresponding Professional Information
SAHPRA website: https://pi-pil-repository.sahpra.org.za/

BIOZANE 0,25

PASIëNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS:
S5

BIOZANE 0,25 tablette
Alprasolam
BIOZANE 0,25 bevat suiker.
BIOZANE 0,25 bevat 100,0 mg laktosemonohidraat per tablet

Lees hierdie hele pamflet noukeurig deur voordat jy begin om BIOZANE 0,25 te neem.
- Hou hierdie pamflet. Dit mag nodig wees dat jy dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief vir jou dokter of jou apteker.
- BIOZANE 0,25 is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as joune.

Wat in hierdie pamflet is
1. Wat BIOZANE 0,25 is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy BIOZANE 0,25 neem
3. Hoe om BIOZANE 0,25 te neem
4. Moontlike newe-effekte
5. Hoe om BIOZANE 0,25 te bewaar
6. Inhoud van die pak en ander inligting

1. Wat BIOZANE 0,25 is en waarvoor dit gebruik word

BIOZANE 0,25 is ’n kalmeermiddel wat die aktiewe bestanddeel alprasolam bevat. Dit behoort aan ŉ groep medisyne wat bensodiasepiene genoem word. Bensodiasepiene beïnvloed chemiese aktiwiteit in die brein om slaap te bevorder en angs en bekommernis te verminder.
BIOZANE 0,25-tablette word gebruik vir die korttermynverligting van simptome van angs. Dit word ook gebruik vir die behandeling van angsversteurings, angs wat verband hou met depressie, depressie en paniekversteurings.

2. Wat jy moet weet voordat jy BIOZANE 0,25 neem

Moenie BIOZANE 0,25 neem nie:
- indien jy hipersensitief (allergies) vir alprasolam of vir enige van die ander bestanddele van BIOZANE 0,25 (gelys in afdeling 6) is.
- indien jy swanger is, kraam of as jy borsvoed.
- indien jy aan ’n siekte genaamd myasthenia gravis ly waartydens jy baie swak en moeë spiere het.
- indien jy aan erge borsprobleme of asemhalingsprobleme ly.
- indien jy ernstige lewerprobleme het.
- indien jy ’n oogtoestand het wat nouhoekgloukoom genoem word.
- indien jy aan ’n toestand genaamd skisofrenie ly.
- indien jy psigoties is, aan geestelike depressie ly of as jy gedagtes het om jou eie lewe te neem.
- indien jy in ’n koma is, aan akute longprobleme ly of as jy aan ’n toestand genaamd slaapapnee ly.
- indien jy jonger as 18 jaar is.
- indien jy medikasie soos ketokonasool of soortgelyke medisyne gebruik om swaminfeksies te behandel.
- indien jy antiretrovirale protease inhibeerdermedisyne neem wat gebruik word in die behandeling van MIV, ketakonasool, itrakonasool of soortgelyke medisyne wat gebruik word om swaminfeksies te behandel.

Waarskuwings en voorsorgmaatreëls
Wees besonder versigtig met BIOZANE 0,25:
- indien jy aan sekere tipes depressie ly (aangesien die gebruik van BIOZANE 0,25 nie vasgestel is nie)
- indien jy psigoties is of aan geestelike depressie ly, moet jy nie BIOZANE 0,25 gebruik nie, tensy jy baie angstig is.
- indien jy aan paniekversteurings ly wat met sekere tipes depressie gepaardgaan, mag BIOZANE 0,25 selfmoordgedagtes of planne na vore bring.
- indien jy probleme met jou longe, niere of lewer het.
- Daar is ’n moontlikheid om afhanklikheid (verslawing) te ontwikkel indien jy BIOZANE 0,25 vir lang tydperke drink of as jy hoë dosisse neem. Die risiko om aan BIOZANE 0,25 verslaaf te raak is ook groter indien jy in die verlede dwelms of alkohol misbruik het.
- indien jy aan BIOZANE 0,25 verslaaf is en jy probeer om dit te vinnig te staak, kan onttrekkingsimptome soos hoofpyn, spierpyn, uiterste angs, spanning, rusteloosheid, verwardheid en prikkelbaarheid ervaar word.
- In erge gevalle kan die volgende simptome voorkom: ’n geestelike toestand waar jy verwyder van jou omgewing voel, alledaagse klanke klink baie harder as wat dit behoort, gevoelloosheid of tinteling van die hande en voete, hipersensitiwiteit vir lig, geraas en fisiese kontak, hallusinasies of epileptiese aanvalle.
- Onttrekkingsimptome kan voorkom as BIOZANE 0,25 skielik gestaak word. Behandeling moet geleidelik verminder word.
- Onttrekkingsimptome sluit die volgende in: algemene ongelukkigheid, slapeloosheid, buik- en spierkrampe, braking, sweet, bewerigheid en skielike en onwillekeurige spiersametrekkings (stuiptrekkings).
- indien jy aan epilepsie ly, kan BIOZANE 0,25 toevalle veroorsaak. Toevalle kan ook voorkom as jy BIOZANE 0,25 skielik stop.
- indien jy BIOZANE 0,25 te vinnig stop, is daar ’n risiko dat die simptome wat gelei het tot die behandeling met BIOZANE 0,25 in ’n erger mate kan terugkom. Dit word dus aanbeveel dat die dosis geleidelik verlaag word.
- indien jy ’n geskiedenis van alkohol- of dwelmmisbruik het, moet BIOZANE 0,25 uiters versigtig gebruik word.
- Die duur van die gebruik van BIOZANE 0,25 moet so kort as moontlik wees. As dit vir angs geneem word, moet dit nie langer as agt tot twaalf weke gebruik word nie, die afskaalproses ingesluit.
- indien jy BIOZANE 0,25 vir lang tydperke gebruik, kan die effektiwiteit van die hipnotiese effekte minder wees.
- indien BIOZANE 0,25 deur bejaarde en verswakte pasiënte geneem word, moet hulle baie versigtig gemonitor word vir newe-effekte soos lomerigheid en spierswakheid wat hierdie pasiënte kan laat val en ernstige beserings kan opdoen.
- Dit is bekend dat reaksies soos rusteloosheid, agitasie, geïrriteerdheid, aggressiwiteit, delusies, woede, nagmerries, hallusinasies, onvanpaste gedrag en ander nadelige gedragseffekte voorkom wanneer bensodiasepiene gebruik word. Hierdie reaksies is meer geneig om in kinders en bejaardes voor te kom. Indien dit voorkom, moet die gebruik van BIOZANE 0,25 gestaak word.
- Die gebruik van BIOZANE 0,25 saam met pynmedikasie wat sekere tipe middels genaamd opioïede bevat, kan lomerigheid, oneffektiewe asemhaling, koma en sterftes veroorsaak. Indien dit nie vermy kan word om hierdie twee tipes middels saam te neem nie, moet die laagste effektiewe dosis van die pynmedikasie gebruik word en die duur van die behandeling moet so kort as moontlik wees.
- Die gebruik van bensodiasepiene soos BIOZANE 0,25 kan ’n swak vermoë om nuwe inligting te onthou veroorsaak wat kan lei tot beperkte of totale onvermoë om gebeurtenisse te onthou en dit is dus nodig dat daar ononderbroke slaap van 7-8 uur na die gebruik van hierdie medikasie moet wees.
- Indien jy deur ’n tydperk van hartseer gaan, sal die nodige sielkundige aanpassing dalk nie bereik word nie
- Die gebruik van BIOZANE 0,25 kan tot episodes van geestesongesteldheid lei wat gekenmerk word deur periodes van gevoel van intense opgewondenheid en geluk, delusies en ooraktiwiteit.
- indien jy ander middels gebruik wat die sentrale senuweestelsel onderdruk, kan die newe-effekte soos lomerigheid, oneffektiewe asemhaling en stadige hartfunksie versterk word.
- indien die wande van die are in jou brein verdik en verhard is (arteriosklerose) moet BIOZANE 0,25 versigtig gebruik word.

Kinders
Moenie BIOZANE 0,25 aan kinders jonger as 18 jaar oud gee nie, want dit is onwaarskynlik dat dit veilig sal wees.

Ander medisyne en BIOZANE 0,25
Vertel altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem (waaronder alle komplementêre of tradisionele medisyne).
- antidepressante bv. imipramien en desimipramien, fluoksetien, sertralien
- pynmedikasie as wat opioïede bevat
- sedeermiddels soos ander bensodiasepiene
- alkohol en ander sentralesenustelselonderdrukkers
- verlaag die dosis BIOZANE 0,25 indien jy medikasie soos fluvoksamien (vir depressie) en simetidien (vir maagsere) gebruik.
- orale voorbehoedmiddels
- diltiasem (medisyne vir hoë bloeddruk)
- antibiotika soos eritromisien
- teenswammiddels (soos ketokonasool, itrakonasool)
- MIV-medisyne (bv. ritonavir)
- digoksien (om harttoestande te behandel)

BIOZANE 0,25 met alkohol
Dit is belangrik om geen alkohol te drink terwyl jy BIOZANE 0,25 neem nie, aangesien alkohol die effek van die medisyne versterk.

Swangerskap en borsvoeding
Indien jy swanger is of borsvoed, dink dat jy dalk swanger kan wees of beplan om ’n baba te hê, moet jy jou dokter, apteker of ander gesondheidsorgverskaffer om advies raadpleeg voordat jy hierdie medisyne neem.

Motorbestuur en gebruik van masjinerie
Dit is nie altyd moontlik om te voorspel tot watter mate BIOZANE 0,25 met jou daaglikse aktiwiteite kan inmeng nie. Jy moet sorg dat jy, totdat jy weet hoe BIOZANE 0,25 jou beïnvloed, nie ’n voertuig bestuur of masjiene hanteer nie.
BIOZANE 0,25 kan lomerigheid of duiseligheid veroorsaak.
Pasiënte wat BIOZANE 0,25 neem, moet aangeraai word om nie motorvoertuie te bestuur of gevaarlike masjinerie te hanteer, of gevaarlike hoogtes te klim nie totdat bepaal is dat hulle nie lomerig of duiselig word terwyl hulle BIOZANE 0,25 kry nie. In hierdie situasies kan swak besluitneming tot ongelukke lei.

BIOZANE 0,25 bevat laktosemonohidraat
Pasiënte met die skaars oorerflike probleem van onverdraagsaamheid vir galaktose, die Lapp laktasetekort of wanabsorpsie van glukose/galaktose, moet nie hierdie medisyne gebruik nie.

3. Hoe om BIOZANE 0,25 te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem BIOZANE 0,25 altyd presies soos wat jou dokter of apteker vir jou gesê het. Raadpleeg jou dokter of apteker indien jy nie seker is nie.
Die gewone dosis BIOZANE 0,25 verskil van persoon tot persoon. Vir pasiënte wat hoër dosisse nodig het, sal jou dokter sal die regte dosis vir jou kies.

A. Vir angs:
Die gewone aanvangsdosis is 0,25 mg tot 0,5 mg drie keer per dag. Jou dokter kan jou dosis verhoog indien dit nodig is. Die dosis is egter gewoonlik nie meer as 4,0 mg per dag nie, gegee as verdeelde dosisse.

B. Vir gemengde angs/depressie - angs saam met depressie:
Die gewone aanvangsdosis is 0,5 mg drie keer per dag. Jou dokter kan jou dosis verhoog indien dit nodig is. Die dosis is egter gewoonlik nie meer as 4,5 mg per dag nie, gegee as verdeelde dosisse.

C. Vir paniekversteurings:
Die gewone aanvangsdosis is 0,5 mg tot 1,0 mg met slaaptyd of 0,5 mg drie keer per dag. Jou dokter kan jou dosis verhoog indien dit nodig is. Die dosis is egter gewoonlik nie meer as 10,0 mg per dag nie.

D. Vir bejaarde pasiënte of saam met ‘n uitmergelende siekte:
Die gewone aanvangsdosis is 0,25 mg twee of drie keer per dag. Jou dokter kan jou dosis verhoog indien dit nodig is. Die dosis is egter gewoonlik nie meer as 0,75 mg per dag nie.

Jou dokter sal vir jou sê hoe lank jou behandeling met BIOZANE 0,25 sal duur. Moenie behandeling vroeg staak nie, want onttrekkingsimptome kan voorkom na ’n vinnige verlaging of skielike staking van BIOZANE 0,25. Dosisse moet stadig verlaag word. Vertel vir jou dokter of apteker indien jy die indruk het dat die effek van BIOZANE 0,25 te sterk of te swak is.

Indien jy meer BIOZANE 0,25 geneem het as wat jy moes
Raadpleeg jou dokter of apteker in geval van oordosering. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien jy vergeet om BIOZANE 0,25 te neem
Indien jy vergeet het om ’n dosis te neem, neem dit sodra as wat jy onthou. Neem dan al die oorblywende dosisse vir daardie dag met gereelde tussenposes. Moenie ’n dubbele dosis neem om vir vergete individuele dosisse op te maak nie.

Indien jy ophou om BIOZANE 0,25 te neem
Moenie behandeling vroeg staak nie, want onttrekkingsimptome kan voorkom na ’n vinnige verlaging of skielike staking van BIOZANE 0,25. Dosisse moet stadig verlaag word.

4. Moontlike newe-effekte

BIOZANE 0,25 kan newe-effekte veroorsaak.
Nie al die newe-effekte wat vir BIOZANE 0,25 aangemeld is, is in hierdie pamflet opgeneem nie. Indien jou algemene gesondheidstoestand versleg of indien jy enige newe-effekte ervaar terwyl jy BIOZANE 0,25 neem, moet jy jou gesondheidsorgverskaffer asseblief om advies raadpleeg.

Newe-effekte van BIOZANE 0,25 kan onder meer die volgende insluitend:
Gereeld:
- swak of geen eetlus nie
- verwardheid, depressie, prikkelbaarheid, angs, geheueverlies, probleme om aandag te gee, senuagtigheid
- veranderinge in seksuele begeerte; seksuele disfunksie
- slaapversteurings soos oormatige slaap of onvermoë om te slaap, moegheid, gebrek aan energie
- duiseligheid, swak balans, verlies aan beheer van volle liggaamlike bewegings (ataksie), bewerigheid
- hoofpyn
- onduidelike uitspraak van woorde (disartrie)
- velirritasie
- versteurde visie (sien nie helder nie)
- naarheid, hardlywigheid, droë mond

Minder gereeld:
- voel geïrriteerd, aggressie. gemoedsversteuring, hallusinasies, gewelddadige gedrag, disinhibisie, slaapstversteuring, abnormale gedagtes
- veranderinge in seksuele begeerte; seksuele disfunksie
- sleepspraak
- geheueverlies
- versteurings in visie, hoë druk in die oë
- ’n sensasie van swaai en verlies van balans (vertigo), spiertrekkings of -swakheid
- Wanbalans, bewegingsversteurings waar jou spiere onwillekeurig saamtrek (distonie)
- lae bloeddruk
- probleme met asemhaling
- veranderinge in speekselafskeiding, diarree en braking
- abnormale lewerfunksie: lewersiekte wat geel verkleuring van die vel of wit van die oë kan veroorsaak
- velirritasie
- veranderinge in urienfrekwensies, nie in staat om blaas heeltemal leeg te maak nie
- veranderings in menstruasie, ongereelde menstruasie
- veranderings in gewig
- hoër as normale prolaktienvlakke in u bloed

Frekwensie onbekend:
- abnormale denke, aggressie, gemoedsversteurings
- gastro-intestinale versteuring
- wanbalans, bewegingsversteuring waarin die spiere onwillekeurig saamtrek (distonie)
- abnormale lewerfunksie
- swelling onder die vel, swelling van onderbene of hande, fotosensitiwiteitsreaksie (uiterste sensitiwiteit vir UV-strale van die son)
- nie in staat is om die blaas heeltemal leeg te maak nie
- hoë druk in die oë

Indien jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, moet jy jou dokter of apteker asseblief in kennis stel.

Aanmeld van newe-effekte
Praat met jou dokter, apteker of verpleegkundige as jy newe-effekte kry. Jy kan newe-effekte ook by SAROGP (“SAHPRA”) aanmeld met die toepaslike vorm, naamlik **“6.04 Adverse Drug Reaction Reporting Form”** wat aanlyn by SAHPRA se publikasies gekry kan word: 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 0,25 te gee.

5. Hoe om BIOZANE 0,25 te bewaar

Bewaar alle medisyne buite bereik van kinders.
Bewaar benede 25 °C.

6. Inhoud van die pak en ander inligting

Wat BIOZANE 0,25 bevat
- Die aktiewe bestanddeel is 0,25 mg alprasolam in een tablet van 0,25 mg.
- Die ander bestanddele is laktosemonohidraat, mikrokristallyne sellulose, natriumkruiskarmellose, magnesiumstearaat.

Hoe BIOZANE 0,25 lyk en die inhoud van die pak
BIOZANE 0,25 mg-tablette is wit, ovaalvormige, bikonvekse tablette met ’n breeklyn en glad aan die ander kant.
BIOZANE 0,25 is beskikbaar in wit poli-etileenbottels (HDPE) met 100 of 1 000 tablette.
BIOZANE 0,25 is beskikbaar in ALU voelie stulpstroke wat 10 tablette bevat in kartonne van 30 of 100 tablette.

Houer van die registrasiesertifikaat
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Hierdie blad is laas hersien in
03 Junie 2022

Registrasienommer
BIOZANE 0,25: 31/2.6/0012

Toegang tot die toepaslike professionele inligting
SAHPRA webtuiste: https://pi-pil-repository.sahpra.org.za/