SCHEDULING STATUS: S5

PAX-5, 5 mg, tablets

PAX-10, 10 mg, tablets

Diazepam

Contains sugar

PAX-5: Lactose monohydrate 113,1 mg per tablet

PAX-10: Lactose monohydrate 108,3 mg per tablet

Read all of this leaflet carefully before you start taking PAX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PAX 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 PAX is and what it is used for
2. What you need to know before you take PAX
3. How to take PAX
4. Possible side effects
5. How to store PAX
6. Contents of the pack and other information

1. What PAX is and what it is used for

Diazepam as contained in PAX belongs to a group of medicines called benzodiazepines. PAX helps in the treatment of anxiety, muscle spasms.

PAX is a long-acting medicine used for:

- Anxiety
- Muscle spasm (cramps) such as those caused by cerebral spasticity

2. What you need to know before you take PAX

Do not take PAX:

- if you are hypersensitive (allergic) to diazepam or any of the other ingredients of PAX (listed in section 6),
- if you have severe breathing or lung problems,

- if you have severe liver problems,
- if you have a condition called “sleep apnoea syndrome” (where your breathing stops when you are asleep),
- if you have a condition called “myasthenia gravis” (where your muscles are weak and get tired easily),
- if you are addicted to CNS depressants (e.g., tranquilisers, sleep medicine) including alcohol
- if you have problems with phobias (strong fears) or obsessions (troublesome, unwanted and repeated thoughts, ideas or feelings).

Do not use PAX alone to treat depression or anxiety associated with depression.

Warnings and precautions

Take special care with PAX:

- if you regularly drink alcohol and/or CNS depressants or take recreational drugs
- if you have had problems with alcohol or drug abuse in the past
- if you experience total or partial memory loss, memory loss is more likely to occur when taking high doses of PAX
- if you have acute narrow-angle glaucoma (eye disorder where the nerve connecting the eye to the brain is damaged, usually due to high eye pressure).
- if you have impaired liver or kidney function
- if you have difficulty breathing or suffer from a lung disease called chronic obstructive pulmonary disease
- if you are being treated for depression
- if you have suicidal thoughts
- if you have a personality disorder
- if you are elderly or weak, your doctor will decide whether to prescribe a lower dose of PAX for you
- if you suffer from arteriosclerosis (build-up of fats, cholesterol and other substances in and on the artery walls)
- if you have low blood pressure
- if you are suffering from porphyria.

Symptoms such as restlessness, agitation, irritability, aggressiveness, delusion, rages, nightmares, hallucinations, psychoses, inappropriate behaviour and other side effects are known to occur when using PAX. Should this occur, the use of PAX should be discontinued. They are more likely to occur in the elderly.

Patients taking PAX have developed blood disorders and periodic blood counts are recommended.

Tolerance

If after a few weeks you notice that the tablets are not working as well as they did when first starting treatment, you should speak to your doctor.

Dependence

When taking this medicine there is a risk of dependence, which increases with the dose and duration of treatment and also in patients with a history of alcoholism and drug abuse. Therefore, you should take PAX tablets for as short a period of time as possible.

Withdrawal

Treatment should be gradually withdrawn. Withdrawal symptoms occur with PAX tablets even when normal doses are given for short periods of time. See section 3, 'If you stop taking PAX tablets.'

Other medicines and PAX

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

PAX can affect the way some medicines work, and some medicines can affect the way PAX works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- medicines to treat mental health problems (e.g., clozapine, phenothiazines, levomepromazine, olanzapine)
- antidepressants (e.g., fluvoxamine, fluoxetine)
- medicines to relieve anxiety such as other benzodiazepine medicines such as clonazepam, flurazepam and temazepam
- medicines to help you sleep
- strong pain killers such as methadone, morphine or pethidine
- medicines for allergies, which make you sleepy
- medicine to treat Parkinson's disease such as levodopa
- medicines to treat asthma and other breathing disorders (theophylline)
- anaesthetic medicine such as ketamine
- medicines to treat convulsions or epilepsy such as phenytoin or carbamazepine

- medicines to treat stomach problems and heartburn, such as cimetidine, omeprazole, cisapride
- medicines to treat fungal skin infections, such as ketoconazole
- oral contraceptives
- medicines to treat alcohol addiction such as disulfiram
- medicines to treat tuberculosis such as isoniazid
- medicines to treat high blood pressure such as diltiazem
- medicines to treat excessive sleepiness caused by sleep apnoea, narcolepsy, or shift work sleep disorder such as modafinil or armodafinil
- antiviral medicine such as ritonavir
- antibiotics such as erythromycin, clarithromycin
- medicines to treat infections (an antibiotic), such as rifampicin
- anticonvulsant medication, such as carbamazepine
- medicines that block the action of acetylcholine, such as atropine

PAX with drink and alcohol

Do not drink alcohol while you are taking PAX tablets. Alcohol may increase the sedative effects of PAX tablets and make you very sleepy.

Grapefruit juice may increase the amount of diazepam in your blood. If you are elderly, suffer from cirrhosis or any of the conditions listed in section 2, this could possibly increase the sedative effects of PAX tablets and you should speak to your doctor or pharmacist.

Drinks containing caffeine may reduce the effects of PAX.

Pregnancy, breastfeeding and fertility

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 PAX.

The safety of PAX during pregnancy has not been established. There is an increased risk of birth defects to your baby if you take PAX during pregnancy. It can also result in so-called floppy-infant syndrome that is characterised by poor muscle tone, problems with sucking and swallowing, difficulty breathing, and low body temperature.

Special care must be taken when PAX is used during labour and delivery, as high single doses may produce irregularities in your baby's heart rate and muscle tone, poor sucking, reduced

body temperature and moderate breathing problems.

PAX is excreted in breastmilk and should not be used by mothers who are breastfeeding. Data on fertility is not currently available.

Driving and using machines
PAX can make you sleepy, making it difficult to concentrate and slows down your reactions.

It is not always possible to predict to what extent PAX 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 PAX affects you.

PAX contains sugar (lactose monohydrate)
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take PAX
Do not share medicines prescribed for you with any other person.
Always take PAX exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
You should be treated for as short as possible. Treatment should not be longer than 2 -3 months, including the time that you are coming off your tablets. You should consult your health care provider regularly to see if you need to continue your treatment, especially if you are symptom free.

- You will be started with a low dose of PAX. Your doctor will slowly increase it until you are taking the right dose for you. Your doctor will always give the lowest possible dose that works for you.
- Your doctor will want you to take PAX for the shortest possible time.
- The usual adult dose is 5 - 10 mg initially. Depending on the severity of your symptoms, your doctor may prescribe a dose of 5 - 20 mg daily.

If you are elderly or very ill, or weak, or have problems with your liver or kidneys, your doctor may give you a lower dose.

Your doctor will tell you how long your treatment with PAX will last. If you have the impression

that the effect of PAX is too strong or too weak, tell your doctor or pharmacist.

If you take more PAX 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 take too many tablets you may feel sleepy, have difficulty controlling your movements (lack of co-ordination), difficulty breathing, reduced heart rate, have slow or slurred speech or jerky eye movements.

If you forget to take PAX

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

If you stop taking PAX

- Do not stop taking PAX without talking to your doctor.
- When you stop taking PAX, your anxiety may return and you may experience sleeping problems, and you may get withdrawal symptoms, especially if you stop too quickly. For the symptoms you may have, see “Withdrawal symptoms” under section 4 “Possible side effects”.
- When it is time to lower your dose or stop taking PAX, it must be done slowly. This lowers the chance of you having withdrawal symptoms. Your doctor will tell you how to do this.

4. Possible side effects

PAX can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and 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 reaction to PAX. 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:

- being restless, aggressive, angry, irritable or agitated.
- nightmares and seeing or hearing things that re not really there (hallucinations).
- mental problems such as delusions (believing in things that are not real) or losing contact with reality.
- a change in your behaviour that is out of character.
- chest pain which may spread to your neck and shoulders and down your left arm. This may be a sign of a heart attack.
- jaundice (yellowing of your skin or the white of your eyes).
- breathing problems (respiratory depression). Early signs include sudden noisy, difficult and uneven breathing. Your skin may become blue.
- a feeling of fullness in your bladder and urge to pass water, but then difficulty emptying your bladder.

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

Tell your doctor if you notice any of the following:

Less frequent side-effects:

- blood disorders (you may develop sore throats, nose bleeds or infections)
- sleepiness, feeling disorientated
- confusion, depression
- tiredness, muscle weakness, slurred speech
- uncontrollable movements, for example of your hands (tremor)
- emotional withdrawal, headache, dizziness
- memory loss, decreased alertness
- uneven heartbeat, heart failure and cessation of heartbeat (cardiac arrest)
- low blood pressure
- respiratory arrest (cessation of breathing)
- double or blurred vision
- indigestion, nausea, dry mouth
- increased salivation
- constipation, diarrhoea
- changes in how well your liver is working (shown by blood tests)
- feeling dizzy or a spinning sensation
- changes in sexual drive (libido)

- irregular menstruation
- falling and breaking your bones.

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, 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 PAX.

5. How to store PAX

Store all medicines out of reach of children.
Store at or below 25 °C, in a well-closed container.
Protect from light.
Keep in original packaging until required for use.
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 PAX contains

Pax-5:

- The active substance is diazepam 5 mg.
- The other ingredients are Dye Lennon lake yellow no.127 (C.I. 15985), lactose monohydrate, microcrystalline cellulose, powdered vegetable stearine, starch maize.

Pax-10:

- The active substance is diazepam 10 mg.
- The other ingredients are Dye Indigo Carmine Lake (C.I. 73015), lactose monohydrate, microcrystalline cellulose, powdered vegetable stearine, starch maize.

What PAX looks like and contents of the pack

PAX-5: A flat, round, pale orange tablet with bevelled edges, bisected on one side and embossed "C33" on the other side.

PAX-10: A flat, round, blue tablet with bevelled edges, bisected on one side and embossed

"C34" on the other side.

PAX-5: 30 tablets are packed in a clear polyvinylchloride blister strip sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton together with a leaflet. 100, 500 or 1 000 tablets are packed in a white cylindrical polypropylene container with a white linear low density polyethylene cap, together with a polyurethane foam insert and leaflet.

PAX-10: 30 tablets are packed in a clear polyvinylchloride blister strip sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton together with a leaflet.
500 tablets are packed in a white polypropylene container with a white low density polyethylene cap, together with a white polyurethane foam insert.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

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Namibia		
NS3	PAX-10	90/2.6/001099

SKEDULERINGSTATUS: S5

PAX-5, 5 mg, tablette

PAX-10, 10 mg, tablette

Diasepaam

Bevat suiker

PAX-5: Laktosemonohidraat 113,1 mg per tablet

PAX-10: Laktosemonohidraat 108,3 mg per tablet

Lees hierdie hele voubiljet noukeurig deur voordat u PAX begin neem

- Hou hierdie voubiljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter of u apteker.
- PAX is aan u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat in hierdie voubiljet is

1. Wat PAX is en waarvoor dit gebruik word
2. Wat u moet weet voordat u PAX neem
3. Hoe om PAX te neem
4. Moontlike newe-effekte
5. Hoe om PAX te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat PAX en is waarvoor dit gebruik word

Diasepaam soos vervat in PAX behoort tot 'n groep medisyne wat bensodiasepiene genoem word. PAX help met die behandeling van angs, spierspasmas.

PAX is 'n langwerkende medisyne wat gebruik word vir:

- Angs
- Spierspasma (krampe) soos dié wat veroorsaak word deur serebrale spastisiteit

2. Wat u moet weet voordat u PAX neem

Moenie PAX neem nie:

- indien u hipersensitief (allergies) is vir diasepaam of enige van die ander bestanddele van PAX (gelys in afdeling 6),
- indien u ernstige asemhalings- of longprobleme het,

- indien u ernstige lewerprobleme het,
- indien u 'n toestand genaamd "slaapapnee-sindroom" het (waar u asemhaling stop wanneer u slaap),
- indien u 'n toestand genaamd "miastenie gravis" het (waar u spiere swak is en maklik moeg word),
- indien u verslaaf is aan SSS-depressante (bv. kalmeermiddels, slaapmedisyne), insluitend alkohol
- indien u probleme het met fobies (erge vrese) of obsessies (lastige, ongewenste en herhaalde gedagtes, idees of gevoelens).

Moenie PAX alleen gebruik om depressie, of angs wat met depressie geassosieer word, te behandel nie.

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met PAX:

- indien u gereeld alkohol en/of SSS-depressante drink of ontspannings-dwelms gebruik
- indien u in die verlede probleme met alkohol- of dwelmmisbruik gehad het
- indien u totale of gedeeltelike geheueverlies ervaar, geheueverlies is meer geneig om voor te kom wanneer hoë dosisse PAX geneem word
- indien u akute nouhoek-gloukoom het (oogversteuring waar die senuwee wat die oog met die brein verbind, beskadig is, gewoonlik as gevolg van hoë oogdruk).
- indien u 'n ingeperkte lewer- of nierfunksie het
- indien u sukkel om asem te haal of ly aan 'n longsiekte genaamd chroniese obstruktiewe longsiekte
- indien u vir depressie behandel word
- indien u selfdoodgedagtes het
- indien u 'n persoonlikheidsversteuring het
- indien u bejaard of swak is, u dokter sal besluit of u 'n laer dosis PAX voorgeskryf moet word
- indien u aan arteriosklerose ly (opbou van vette, cholesterol en ander stowwe in en op die slagaarwande)
- indien u lae bloeddruk het
- indien u aan porfirie ly.

Dit is bekend dat simptome soos rusteloosheid, opgewerktheid, prikkelbaarheid, aggressiwiteit, wangedagtes, woede, nagmerries, hallusinasies, psigoses, onvanpaste gedrag en ander newe-effekte voorkom wanneer PAX gebruik word. Indien dit gebeur, moet

die gebruik van PAX gestaak word. Dit is meer geneig om by bejaardes voor te kom.

Pasiënte wat PAX neem, het bloedafwykings ontwikkel en periodieke bloedtellings word aanbeveel.

Verdraagsaamheid
Indien u na 'n paar weke agterkom dat die tablette nie so goed werk soos toe hulle die eerste keer met die behandeling begin het nie, moet u met u dokter praat.

Afhanklikheid
By die gebruik van hierdie medisyne is daar 'n risiko van afhanklikheid, wat toeneem met die dosis en duur van die behandeling, en ook by pasiënte met 'n geskiedenis van alkoholisme en dwelmmisbruik. Daarom moet u PAX tablette vir so kort as moontlik neem.

Onttrekking
Behandeling moet geleidelik onttrek word. Onttrekkingsimptome kom voor met PAX tablette, selfs wanneer normale dosisse vir kort tydperke gegee word. Sien afdeling 3, 'Indien u ophou om PAX tablette te neem.'

Ander medisyne en PAX
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
PAX kan die manier waarop sommige medisyne werk, beïnvloed, en sommige medisyne kan die manier waarop PAX werk, beïnvloed.
Lig veral u dokter of apteker in indien u enige van die volgende medisyne neem:

- medisyne vir die behandeling van geestesgesondheidsprobleme (bv. klosapien, fenotiasiene, levomepromasien, olansapien)
- antidepressante (bv. fluvoksamien, fluoksetien)
- medisyne om angs te verlig soos ander bensodiasepien-medisyne soos klonasepaam, flurasepaam en temasepaam
- medisyne om u te help slaap
- Sterk pynstillers soos metadoon, morfien of petidien
- medisyne vir allergieë, wat u slaperig maak
- medisyne om Parkinson se siekte te behandel, soos levodopa
- medisyne vir die behandeling van asma en ander asemhalingsversteurings (teofillien)
- narkosemedisyne soos ketamien

- medisyne vir die behandeling van stuiptrekkings of epilepsie soos fenitoïen of karbamasepien
- medisyne vir die behandeling van maagprobleme en sooibrand, soos simetidien, omeprasool, sisapried
- medisyne vir die behandeling van swam-velinfeksies, soos ketokonasool
- orale voorbehoedmiddels
- medisyne vir die behandeling van alkoholverslawing soos disulfiram
- medisyne vir die behandeling van tuberkulose soos isoniasied
- medisyne vir die behandeling van hoë bloeddruk soos diltiasem
- medisyne vir die behandeling van oormatige slaperigheid wat veroorsaak word deur slaapapnee, narkolepsie of skofwerk-slaapsteurnis soos modafinil of armodafinil
- antivirale medisyne soos ritonavir
- antibiotika soos eritromisien, klaritromisien
- medisyne vir die behandeling van infeksies ('n antibiotikum), soos rifampisien
- antikonvulsie-medikasie, soos karbamasepien
- medisyne wat die werking van asetielcholien blokkeer, soos atropien

PAX saam met drank en alkohol

Moenie alkohol drink terwyl u PAX tablette neem nie. Alkohol kan die kalmerende effekte van PAX tablette verhoog en u baie slaperig maak.

Pomelosap kan die hoeveelheid diasepaam in u bloed verhoog. Indien u bejaard is, ly aan sirrose of enige van die toestande wat in afdeling 2 gelys word, kan dit moontlik die kalmerende effekte van PAX tablette verhoog en moet u dokter of apteker geraadpleeg word.

Drankies wat kafeïen bevat, kan die gevolge van PAX verminder.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, dink u is dalk swanger of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u PAX neem.

Die veiligheid van PAX tydens swangerskap is nie vasgestel nie. Daar is 'n verhoogde risiko vir geboortedefekte vir u baba indien u PAX tydens swangerskap neem. Dit kan ook lei tot sogenaamde slap-baba-sindroom wat gekenmerk word deur swak spiertonus, probleme met suig en sluk, probleme met asemhaling en lae liggaamstemperatuur.

Wees versigtig wanneer PAX tydens kraam en bevalling gebruik word, aangesien hoë enkeldosisse onreëlmatighede in u baba se hartspoed en spiertonus, swak suig, verlaagde liggaamstemperatuur en matige asemhalingsprobleme kan veroorsaak.

PAX word in borsmelk uitgeskei en moet nie gebruik word deur moeders wat borsvoed nie. Data oor vrugbaarheid is tans nie beskikbaar nie.

Bestuur en gebruik van masjinerie
PAX kan u slaperig maak, wat dit moeilik maak om te konsentreer en u reaksies vertraag.

Dit is nie altyd moontlik om te voorspel tot watter mate PAX met u daaglikse aktiwiteite kan inmeng nie. U moet seker maak dat u nie bestuur of masjinerie hanteer voordat u bewus is van die mate waartoe PAX u affekteer nie.

PAX bevat suiker (laktosemonohidraat)
Indien u deur u dokter meegedeel is dat u 'n onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u hierdie medisyne neem.

3. Hoe om PAX te neem
Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.
Neem PAX altyd presies soos u dokter of apteker u aangesê het. Raadpleeg u dokter of apteker indien u nie seker is nie.
U moet vir so kort as moontlik behandel word. Behandeling moet nie langer duur as 2 -3 maande nie, insluitend die tyd wat u die tablette staak. U moet u gesondheidsorgverskaffer gereeld raadpleeg om te sien of u die behandeling moet voortsit, veral indien u simptoom-vry is.

- U sal met 'n lae dosis PAX begin. U dokter sal dit stadig verhoog totdat u die regte dosis vir u neem. U dokter sal altyd die laagste moontlike dosis gee wat vir u werk.
- U dokter sal wil hê u moet PAX vir die kortste moontlike tyd neem.
- Die algemene volwasse dosis is aanvanklik 5 - 10 mg. Afhangende van die erns van u simptome, kan u dokter 'n dosis van 5 - 20 mg daagliks voorskryf.

Indien u bejaard of baie siek of swak is, of probleme met u lewer of niere het, kan u dokter u 'n laer dosis gee.

U dokter sal u inlig hoe lank u behandeling met PAX sal duur. Indien u die indruk het dat die effek van PAX te sterk of te swak is, lig u dokter of apteker in.

Indien u meer PAX neem as wat u moes

In die geval van ‘n oordosis, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Indien u te veel tablette neem, kan u slaperig voel, sukkel om u bewegings te beheer (gebrek aan koördinasie), moeilik asem haal, verlaagde hartspoed hê, stadige of onduidelike spraak of rukkerige oogbewegings hê.

Indien u vergeet om PAX te neem

Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

Indien u ophou om PAX te neem

- Moenie die gebruik van PAX staak sonder om u dokter te raadpleeg nie.
- Wanneer u ophou om PAX te neem, kan u angs terugkeer en u kan slaapprobleme ervaar, en u kan onttrekkingsimptome kry, veral as u te vinnig stop. Vir die simptome wat u mag hê, sien "Onttrekkingsimptome" onder afdeling 4 "Moontlike newe-effekte".
- Wanneer dit tyd is om u dosis te verlaag of op te hou om PAX te neem, moet dit stadig gedoen word. Dit verlaag die kans dat u onttrekkingsimptome ervaar. U dokter sal u inlig hoe om dit te doen.

4. Moontlike newe-effekte

PAX kan newe-effekte hê.

Nie alle newe-effekte wat vir PAX aangemeld is, word in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste effekte ervaar terwyl u PAX neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van PAX en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal,
- veluitslag of jeukerigheid,
- floute.

Dit is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op PAX gehad. U sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:

- rusteloos, aggressief, kwaad, geïrriteerd of opgewerk te wees.
- nagmerries, en dinge sien of hoor wat nie regtig daar is nie (hallusinasies).
- verstandelike probleme soos wangedagtes (glo in dinge wat nie werklik is nie) of kontak met die werklikheid verloor.
- 'n verandering in u gedrag wat buite karakter is.
- borspyn wat na u nek en skouers, en langs u linkerarm af kan versprei. Dit kan 'n teken van 'n hartaanval wees.
- geelsug (vergeling van u vel of die wit van u oë).
- asemhalingsprobleme (respiratoriese depressie). Vroeë tekens sluit in skielike raserige, moeilike en ongelyke asemhaling. U vel kan blou word.
- 'n gevoel van volheid in u blaas en drang om te urineer, maar dan sukkel om u blaas te ledig.

Dit is alles ernstige newe-effekte. U sal dalk dringend mediese hulp nodig hê.

Lig u dokter in indien u enige van die volgende opmerk:

Minder algemene newe-effekte:

- bloedafwykings (u kan seer keel, neusbloeding of infeksies ontwikkel)
- slaperigheid, voel gedisoriënteerd
- verwarring, depressie
- moegheid, spierswakheid, onduidelike spraak
- onbeheerbare bewegings, byvoorbeeld van u hande (bewerasies)
- emosionele onttrekking, hoofpyn, duiseligheid
- geheueverlies, verminderde waaksaamheid
- ongelyke hartklop, hartversaking en staking van hartklop (hartstilstand)
- lae bloeddruk
- asemhaling-stilstand (staking van asemhaling)
- dubbele of versteurde visie
- slegte spysvertering, naarheid, droë mond
- verhoogde speekselvorming
- hardlywigheid, diarree
- veranderinge in hoe goed u lewer werk (getoon deur bloedtoetse)
- duiselig voel of 'n tollende sensasie ervaar
- veranderinge in seksuele drang (libido)

- onreëlmatige menstruasie
- val en u bene breek.

Indien u enige newe-effekte opmerk wat nie in hierdie voubiljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die vorm "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn onder SAHPRA se publikasies gevind kan word: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van PAX te verskaf.

5. Hoe om PAX te bêre

Bêre alle medisyne buite bereik van kinders.
Bêre teen of benede 25 °C, in 'n diggeslote houer.
Beskerm teen lig.
Hou in oorspronklike verpakking totdat dit benodig word vir gebruik.
Moenie gebruik ná die vervaldatum wat op die etiket / karton / bottel vermeld word nie
Neem alle ongebruikte medisyne terug na u apteker.
Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat PAX bevat

Pax-5:

- Die aktiewe bestanddeel is diasepaam 5 mg.
- Die ander bestanddele is “Lennon lake” geel kleursel no.127 (C.I. 15985), laktosemonohidraat, mikrokristallyne sellulose, verpoeierde plantaardige stearien, mieliestysel.

Pax-10:

- Die aktiewe bestanddeel is diasepaam 10 mg.
- Die ander bestanddele is “Indigo Carmine Lake” kleursel (CI 73015), laktosemonohidraat, mikrokristallyne sellulose, verpoeierde plantaardige stearien, mieliestysel.

Hoe PAX lyk en inhoud van die verpakking

PAX-5: 'n Plat, ronde, lig-oranje tablet met afgekante rande, aan die een kant gekeep en met "C33" gedruk aan die ander kant.
PAX-10: 'n Plat, ronde, blou tablet met afgekante rande, aan die een kant gekeep en met "C34" gedruk aan die ander kant.

PAX-5: 30 tablette word verpak in 'n deursigtige polivinielchloried-stulpstrook wat met 'n aluminiumfoelie-agterkant verseël is. Die stulpstroke word saam met 'n voubiljet in 'n buitenste kartonboksie verpak.
100, 500 of 1 000 tablette word verpak in 'n wit silindriese polipropileen-houer met 'n wit lineêre laedigtheid poliëtileendop, tesame met 'n poliuretaan-skuim insetsel en voubiljet.

PAX-10: 30 tablette is verpak in 'n deursigtige polivinielchloried-stulpstrook wat met 'n aluminiumfoelie-agterkant verseël is. Die stulpstroke word saam met 'n voubiljet in 'n buitenste kartonboksie verpak.
500 tablette word verpak in 'n wit polipropileen-houer met 'n wit laedigtheid poliëtileendop, tesame met 'n wit poliuretaan-skuim insetsel.

Nie alle pakke en verpakkingsgroottes word noodwendig bemark nie.

Houer van Registrasiesertifikaat
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