

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,

PATIENT INFORMATION LEAFLET

- 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.

PATIENT INFORMATION LEAFLET

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

PATIENT INFORMATION LEAFLET

- 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

PATIENT INFORMATION LEAFLET

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.

PATIENT INFORMATION LEAFLET

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 are 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)

PATIENT INFORMATION LEAFLET

- 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

PATIENT INFORMATION LEAFLET

“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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