

PATIENT INFORMATION LEAFLET
BROMAZEPAM 3 KIARA / BROMAZEPAM 6 KIARA

SCHEDULING STATUS: S5

BROMAZEPAM 3 KIARA (3 mg, tablets)

BROMAZEPAM 6 KIARA (6 mg, tablets)

BROMAZEPAM

Each BROMAZEPAM 3 KIARA tablet contains sugar (lactose 100 mg).

Each BROMAZEPAM 6 KIARA tablet contains sugar (lactose 100 mg).

Read all of this leaflet carefully before you start using BROMAZEPAM KIARA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- BROMAZEPAM KIARA 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.

1. What BROMAZEPAM KIARA is and what it is used for

- BROMAZEPAM KIARA contains the active substance bromazepam.
- Bromazepam belongs to a group of medicines called benzodiazepines.
- BROMAZEPAM KIARA is used in the treatment of anxiety attacks.

2. What you need to know before you take BROMAZEPAM KIARA

Do not take BROMAZEPAM KIARA

- If you are hypersensitive (allergic) to bromazepam or benzodiazepines or any of the other ingredients of BROMAZEPAM KIARA (listed in section 6).
- If you are pregnant or breastfeeding.
- If you suffer from a muscle disorder called myasthenia gravis.
- If you suffer from acute close-angle glaucoma (increased eye pressure).
- If you have severe breathing problems or lung disease.
- If you have a condition called 'sleep apnoea syndrome' (where your breathing stops when you are asleep).
- If you have severe liver problems.
- If you are using the anti-fungal medicines, itraconazole or ketoconazole, to treat a fungus infection.

Warnings and precautions

Tell your doctor:

- If you suffer from lung disease and limited lung capacity.
- If you suffer from impairment of renal (kidney) or hepatic (liver) function.
- If you have a history of alcohol or drug abuse.
- If you suffer from depression and are taking anti-depressants.
- If you sometimes feel suicidal (thoughts of wanting to kill yourself).

- If you are taking medicines for pain relief called opioids (naloxone, morphine and fentanyl).
- If it feels like BROMAZEPAM KIARA is no longer working as well as it used to (the effect may be reduced after repeated use over a few weeks).

Elderly patients and debilitated patients are more susceptible to oversedation and respiratory depression.

There is a potential for abuse and the development of physical and physiological dependence, especially with prolonged use and high doses.

If you develop any of the following symptoms, please inform your doctor immediately:

Loss of sense of reality, feeling restless, feeling agitated or irritated, feeling aggressive, having fits of rage, having nightmares, increased hearing capability, numbness and tingling of arms and legs, hypersensitivity to light, noise and physical contact, hallucinations (hearing, seeing or feeling things that are not there), behaving inappropriately (e.g., loss of inhibition and making reckless decisions) or epileptic seizures (fits). These symptoms may occur more commonly in children and the elderly.

Before taking BROMAZEPAM KIARA, ensure that you will be able to have uninterrupted sleep for several hours, or you could suffer from a condition called “anterograde amnesia”, which is a condition where it is difficult to make new memories and may also result in inappropriate behaviour like loss of inhibition and making reckless decisions.

Other medicines and BROMAZEPAM KIARA

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

Tell your doctor or pharmacist if you are currently using:

- Antidepressants, antihistamines (hay fever treatment) and antipsychotic treatment.
- Medicines used to help you sleep (e.g., anxiolytics or sedatives).
- Cisapride and cimetidine (treatment used in gastrointestinal disorders).
- Opioid analgesics (naloxone, morphine and fentanyl).
- Carbamazepine (anti-epileptic medication).
- High blood pressure treatment (trimethaphan and calcium channel blockers).
- Propranolol (used to treat high blood pressure, tremors, and chest pain).
- Fluvoxamine (used to treat obsessive compulsive disorder and anxiety).
- An oral contraceptive (the “pill”).
- Medicine used for treating infections, including HIV (for example, protease inhibitors).
- Itraconazole or ketoconazole (antifungal agent) (see **Do not take BROMAZEPAM KIARA**).

Concomitant use of BROMAZEPAM KIARA and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness,

difficulties in breathing (respiratory depression), and coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

Your doctor and pharmacist will have more information on medicines to be careful with or to avoid while taking BROMAZEPAM KIARA.

BROMAZEPAM KIARA with food and drink and alcohol

The use of alcohol with BROMAZEPAM KIARA is not advised.

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 BROMAZEPAM KIARA.

BROMAZEPAM KIARA should not be used during pregnancy.

You should either avoid taking BROMAZEPAM KIARA if you are breastfeeding or discontinue breastfeeding. It is not known if BROMAZEPAM KIARA can affect an unborn baby or pass into breast milk.

Driving and using machinery

Caution is advised when driving a motor vehicle, climbing dangerous heights or operating dangerous machinery. The use of BROMAZEPAM KIARA can lead to drowsiness, memory loss, impaired decision making, impaired concentration or impaired muscular

function, which can lead to accidents. These side effects are more likely to occur at the beginning of treatment, when the dose is increased, with lack of sleep or with the use of alcohol.

BROMAZEPAM KIARA contains sugar (lactose monohydrate)

BROMAZEPAM KIARA tablets contain an ingredient called lactose (milk sugar). If you have severe lactose intolerance, galactose intolerance, or glucose-galactose malabsorption, tell your doctor before taking BROMAZEPAM KIARA.

3. How to take BROMAZEPAM KIARA

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

Always take BROMAZEPAM KIARA exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

Treatment should be started with the lowest recommended dose.

The maximum dose should not be exceeded.

The usual dose is 1,5 to 3 mg three times daily.

Severe cases, especially in hospital:

6 to 12 mg two or three times daily.

These amounts are average recommendations and the dosage should be individually determined. Treatment of outpatients in general begins with the lowest dose, gradually

increasing if necessary to optimum level. According to progress in therapy, the dosage can usually be gradually reduced and then stopped.

Duration of treatment:

Treatment should be as short as possible. You should be assessed regularly and the need for continued treatment should be re-evaluated especially when you are symptom free. The overall duration of treatment, generally, should not be more than 8 to 12 weeks, including a tapering-off process.

If you take more BROMAZEPAM KIARA 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 BROMAZEPAM KIARA

Do not take / receive a double dose to make up for forgotten individual doses. If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you stop taking BROMAZEPAM KIARA

Do not stop taking your tablets without consulting your doctor. The frequency of taking BROMAZEPAM KIARA should slowly be decreased (tapered off). This can lead to mood changes, anxiety, insomnia and restlessness.

4. Possible side effects

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

If any of the following happens, stop taking BROMAZEPAM KIARA 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.
- Blurred vision or other changes in vision.
- Seizures.

These are all very serious side effects. If you have them, you may have had a serious reaction to BROMAZEPAM KIARA. You may need urgent medical attention or hospitalisation.

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

- Yellow skin or yellow eyes.
- Tummy pain which is sore when you press it (tenderness) on the right side just below your ribs.
- A feeling of sickness (nausea) that is unexplained.

- Tiredness.
- Feeling that you are coming down with flu.

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

The following side effects may be experienced:

Frequent side effects include:

- Feeling drowsy or sleepy.
- Dizziness.
- Headache.
- Light-headedness.
- Clumsiness or unsteadiness.
- Slurred speech.

Less frequent side effects include:

- Lack of memory of events taking place after BROMAZEPAM KIARA was taken.
- Anxiety, mental depression, irritability, nervousness, unusual excitement, seizures (fits) and tremor.
- Disorientation or confusion.
- Being restless, angry, agitated or feeling full of rage.
- Nightmares.
- Having strange and unusual thoughts, hearing or seeing things that do not exist.
- A change in your behaviour that is out of character.

- Fast, pounding or irregular heartbeat.
- More mucus than normal in your lungs.
- More saliva than usual.
- Abdominal or stomach cramps/pain, constipation, diarrhoea, dryness of mouth or increased thirst and nausea or vomiting.
- Muscle spasm.
- Difficulty passing water (urinating).
- Changes in your sex drive.

The frequency of the following side effects are unknown:

- Unexplained bleeding and/or bruising; increased risk of infections, e.g., chills, fever, sore throat, unusual tiredness or weakness, mouth ulcers and pale skin, which are the symptoms of a condition called blood dyscrasias.
- False beliefs that cannot be changed by facts (abnormal thinking).
- Loss of sense of reality, disorientation, aggressive behaviour, hallucinations, false sense of well-being, feeling very happy (euphoria), feeling emotional.
- Getting addicted to or dependent on BROMAZEPAM KIARA.
- Withdrawal syndrome (see **If you stop taking BROMAZEPAM KIARA**).
- Being less alert.
- Double vision (diplopia).
- Heart problems including heart failure (may be seen as breathlessness, swelling of the ankles, cough, tiredness and a racing heart) and cardiac arrest.
- Low blood pressure.

- Breathing problems (respiratory depression). Early signs include suddenly noisy, difficult and uneven breathing. Your skin may become blue.
- Skin rashes, itchy skin and reddening of the skin.
- Uncontrolled movements of body, including eyes.
- Weak muscles.
- Patients taking BROMAZEPAM KIARA are at risk of falling and breaking bones. This risk is increased in the elderly and those taking other sedatives (including alcohol).

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 BROMAZEPAM KIARA.

5. How to store BROMAZEPAM KIARA

Store at or below 25 °C and protect from light.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use the tablets after the expiry date printed on the blisters and containers.

Decomposed products may be toxic.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

Keep blisters in the outer carton until required for use.

6. Contents of the pack and other information

What BROMAZEPAM KIARA contains

Each BROMAZEPAM 3 KIARA tablet contains 3 mg bromazepam.

Each BROMAZEPAM 6 KIARA tablet contains 6 mg bromazepam.

Inactive ingredients:

BROMAZEPAM 3 KIARA:

Lactose, maize starch, povidone K30, purified talc, magnesium stearate and Spectracol erythrosine lake.

BROMAZEPAM 6 KIARA:

Lactose, maize starch, povidone K30, purified talc, magnesium stearate and green apple deep colour powder.

What BROMAZEPAM KIARA looks like and contents of the pack

BROMAZEPAM 3 KIARA:

Round, pink, mottled, flat tablet, scored on one side, 8 mm in diameter.

BROMAZEPAM 6 KIARA:

Round, green, mottled, flat tablet, scored on one side, 8 mm in diameter.

Supplied in amber glass bottles, white HDPE securitainers or blisters of 30, 60, 100, 500 or 1000 tablets. Not all pack sizes are marketed.

Holder of the Certificate of Registration

Kiara Health (Pty) Ltd

72 Steel Road

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Kempton Park, 1619

South Africa

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Registration Number

BROMAZEPAM 3 KIARA: S/2.6/149

BROMAZEPAM 6 KIARA: S/2.6/150

Additional countries registration details:

Country	Product name	Scheduling status (or Category of distribution)	Registration number
Namibia	BROMAZEPAM 3 KIARA	NS3	90/2.6/001454
	BROMAZEPAM 6 KIARA	NS3	90/2.6/001455
Botswana	BROMAZEPAM 3 KIARA	1C	B9308850
	BROMAZEPAM 6 KIARA	1C	B9308855
Zimbabwe	BROMAZEPAM 3 KIARA	P.P	96/13.2.2/3060
	BROMAZEPAM 6 KIARA	P.P	96/13.2.2/3061

ATC Code: N05BA08 Benzodiazepine Derivatives

Pharmacological classification: 13.2.2 – Anxiolytics (Zimbabwe)

Name and address of manufacturer:

Kiara Health (Pty) Ltd

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