SCHEDULING STATUS: S5

1. NAME OF THE MEDICINE
BROMAZEPAM 3 KIARA (3 mg, tablets)
BROMAZEPAM 6 KIARA (6 mg, tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each BROMAZEPAM 3 KIARA tablet contains 3 mg bromazepam.
Each BROMAZEPAM 6 KIARA tablet contains 6 mg bromazepam.

Each BROMAZEPAM 3 KIARA tablet contains sugar (lactose 100 mg).
Each BROMAZEPAM 6 KIARA tablet contains sugar (lactose 100 mg).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
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.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Anxiety states.
BROMAZEPAM KIARA is only indicated when the disorder is severe, disabling or when the individual is subject to extreme stress.

4.2 Posology and method of administration
Posology
Treatment should be started with the lowest recommended dose. The maximum dose should not be exceeded.

Average dose for outpatient therapy:
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. The patient should be assessed regularly and the need for continued treatment should be re-evaluated especially when the patient is symptom free. The overall duration of treatment, generally, should not be more than 8 to 12 weeks, including a tapering off process. In certain cases, extension beyond the maximum treatment period may be necessary. If so, it should not take place without re-evaluation of the patient's status.

4.3 Contraindications
- Hypersensitivity to bromazepam, any other benzodiazepine or any of the ingredients, including excipients.
- Myasthenia gravis.
- Acute, closed-angle glaucoma.
- Severe respiratory insufficiency.
- Sleep apnoea syndrome.
- Severe hepatic insufficiency (benzodiazepines are not indicated to treat patients with severe hepatic insufficiency as they may cause encephalopathy).
- The use of itraconazole or ketoconazole in combination with BROMAZEPAM KIARA is contraindicated (see section 4.5).

4.4 Special warnings and precautions for use
Amnesia:
BROMAZEPAM KIARA may induce anterograde amnesia. The condition occurs most often several hours after ingesting BROMAZEPAM KIARA and therefore, to reduce the risk, patients should ensure that they will be able to have an uninterrupted sleep of several hours. Amnestic effects may be associated with inappropriate behaviour (see also section 4.8).

Psychiatric and paradoxical reactions:
Reactions like restlessness, agitation, irritability, aggressiveness, delusion, rages, nightmares, hallucinations, psychoses, inappropriate behaviour and other adverse behavioural effects are known to occur when using BROMAZEPAM KIARA. Should this occur, use of BROMAZEPAM KIARA should be discontinued.

They are more likely to occur in children and the elderly.

Duration of treatment:
The duration of treatment should be as short as possible (see section 4.2 Posology) and should not exceed 8 – 12 weeks, including a tapering-off process. Extension beyond these periods should not take place without re-evaluation of the situation.

It may be useful to inform the patient, when treatment is started, that it will be of limited duration, and to explain precisely how the dosage will be progressively decreased. Moreover, it is important that the patient should be aware of the possibility of rebound phenomena, thereby minimising anxiety over such symptoms, should they occur while BROMAZEPAM KIARA is being discontinued.

When benzodiazepines with a long duration of action are being used, it is important to warn against changing to a benzodiazepine with a short duration of action, like BROMAZEPAM KIARA, as withdrawal symptoms may develop.

Concomitant use of alcohol / CNS depressants:
The concomitant use of BROMAZEPAM KIARA with alcohol or / and CNS depressants should be avoided. Such concomitant use has the potential to increase the clinical effects of BROMAZEPAM KIARA, possibly including severe sedation, clinically relevant respiratory and/or cardiovascular depression (see section 4.5).

The patient should be checked regularly at the start of treatment in order to minimise the dosage and/or the frequency of administration and to prevent overdose due to accumulation.

Risk from concomitant use of opioids:
Concomitant use of BROMAZEPAM KIARA and opioids may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing of sedative medicines such as benzodiazepines or related medicines such as BROMAZEPAM KIARA with opioids should be reserved for patients for whom alternative treatment options are not possible. If a decision is made to prescribe BROMAZEPAM KIARA concomitantly with opioids, the lowest effective dose should be used, and the duration of treatment should be as short as possible (see also general dose recommendation in section 4.2). The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their caregivers (where applicable) to be aware of these symptoms (see section 4.5).

Tolerance:
Some loss of efficacy to the effects of BROMAZEPAM KIARA may develop after repeated use for a few weeks.

Specific patient groups:
BROMAZEPAM KIARA should not be given to children without careful assessment of the need to do so; the duration of treatment must be kept to a minimum.

Caution should be exercised with the elderly and debilitated who are at particular risk of over-sedation, respiratory depression and ataxia. The initial oral dosage should be reduced in these patients.

A lower dose is also recommended for patients with chronic respiratory insufficiency due to the risk of respiratory depression.

Patients suffering from impairment of renal function.

BROMAZEPAM KIARA is not indicated to treat patients with severe hepatic insufficiency as it may precipitate encephalopathy (see section 4.3).

BROMAZEPAM KIARA is not recommended for the primary treatment of psychotic illness.

BROMAZEPAM KIARA should not be used alone to treat depression, or anxiety with depression, as suicide may be precipitated in such patients. Therefore, BROMAZEPAM KIARA should be used with caution and the prescription size should be limited in patients with signs and symptoms of a depressive disorder or suicidal tendencies.

BROMAZEPAM KIARA should be used with extreme caution in patients with a history of alcohol or drug abuse (see section 4.5).

Dependence:
There is a potential for abuse and the development of physical and psychological dependence, especially with prolonged use and high doses. The risk of dependence is also greater in patients with a history of alcohol or drug abuse. Once physical dependence has developed, abrupt termination of treatment will be accompanied by withdrawal symptoms. These may consist of headaches, diarrhoea, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability.

In severe cases, the following symptoms may occur:
De-realisation, depersonalisation, hyperacusis, numbness and tingling of extremities, hypersensitivity to light, noise and physical contact, hallucinations or epileptic seizures.

Rebound insomnia and anxiety:
A transient syndrome whereby the symptoms that led to treatment with BROMAZEPAM KIARA recur in an enhanced form, may occur on withdrawal of treatment. It may be accompanied by other reactions including mood changes, anxiety or sleep disturbances and restlessness. Since the risk of withdrawal or rebound phenomena is greater after abrupt discontinuation of treatment, it is recommended that the dosage is decreased gradually.

Lactose intolerance:
BROMAZEPAM KIARA contains lactose. Patients with the rare hereditary conditions of galactose intolerance e.g., galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take BROMAZEPAM KIARA.

4.5 Interactions with other medicines and other forms of interaction
Pharmacodynamic interaction
The use of other addictive medication, especially central nervous system (CNS) depressants with habituating properties can increase the risk of habituation with BROMAZEPAM KIARA (see section 4.8).

BROMAZEPAM KIARA produces an additive effect when co-administered with alcohol or other CNS depressants. The use of CNS depressants and alcohol concomitantly with BROMAZEPAM KIARA can also increase the risk of apnoea. Concomitant intake with alcohol is not recommended.

BROMAZEPAM KIARA should be used with caution when combined with other CNS depressants. Enhancement of the central depressive effect or cardiovascular depression may occur in case of concomitant use with antipsychotics (neuroleptics), anxiolytics/sedatives, some anti-depressant agents, opioids, anticonvulsants and sedative H1-antihistamines.

The sedative effect of BROMAZEPAM KIARA may also be enhanced by cisapride.

Warning for overdose of other central nervous system depressants, including alcohol (see section 4.9).

Special care should be made with medicines depressing respiratory function such as opioids (analgesics, antitussives, substitutive treatments), notably in elderly people.

Opioids:
The concomitant use of sedative medicines such as benzodiazepines or related medicines such as BROMAZEPAM KIARA with opioids increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effects. The dose and duration of concomitant use should be limited (see section 4.4).

When opioid analgesics are administered with BROMAZEPAM KIARA, the dosage of the opioid analgesic should be reduced by at least one third.

Concurrent use of carbamazepine and BROMAZEPAM KIARA may lead to an increase of the carbamazepine concentrations and monitoring of carbamazepine blood concentrations is recommended.

Pharmacokinetic interaction
Pharmacokinetic interactions can occur when BROMAZEPAM KIARA is administered along with medicines that inhibit the hepatic enzyme CYP3A4 by increasing the plasma levels of BROMAZEPAM KIARA.

Co-administration of cimetidine, a known inhibitor of many isozymes of the cytochrome P450 enzyme system (specifically CYP3A3/4, CYP2C9, CYP1A2, CYP2C18 and CYP2D6) may prolong the elimination half-life of bromazepam through a substantially reduced clearance of approximately 50 %.

Co-administration of propranolol prolongs the elimination half-life of bromazepam by approximately 20 % and results in a non-significant increase in bromazepam clearance.

Co-administration with fluvoxamine, an inhibitor of CYP1A2, significantly increases bromazepam exposure (AUC, 2,4-fold) and elimination half-life (1,9-fold).

BROMAZEPAM KIARA does not induce oxidative hepatic enzymes at therapeutic doses.

Co-administration of BROMAZEPAM KIARA with oral oestrogen-containing contraceptives, fluvoxamine, cimetidine and nefazodone may lead to an increase in BROMAZEPAM KIARA concentrations.

The co-administration of BROMAZEPAM KIARA with strong CYP3A4 inhibitors (for example azole antifungals, protease inhibitors or some macrolides) should be made with caution and a substantial dose reduction considered.

The use of itraconazole or ketoconazole in combination with BROMAZEPAM KIARA is contraindicated: it may inhibit the metabolism of BROMAZEPAM KIARA, leading to delayed elimination and increased plasma concentrations (see section 4.3).

In the case of narcotic analgesics, enhancement of the euphoria may also occur leading to an increase in psychic medicine dependence.

Hypotension-producing medications may potentiate the hypotensive effects of benzodiazepine pre-anaesthetics when used in surgery and dosage adjustments may be necessary.

4.6 Fertility, pregnancy, and lactation
Pregnancy:
The safety of BROMAZEPAM KIARA in pregnancy has not been established. The medicine should be used judiciously during pregnancy and preferably avoided. When given during labour, it crosses the placenta and may cause the floppy-infant syndrome characterised by central respiratory depression, hypothermia and poor sucking.

Lactation:
BROMAZEPAM KIARA should not be administered to lactating mothers.

4.7 Effects on the ability to drive and operate machinery
Patients should be advised, particularly at the initiation of therapy, not to drive a motor vehicle, climb dangerous heights or operate dangerous machinery. Sedation, amnesia, impaired concentration and impaired muscular function may adversely affect the ability to drive or to use machines. If insufficient sleep duration occurs, the likelihood of impaired alertness may be increased (see also section 4.4). This effect is increased if the patient has taken alcohol. In these situations, impaired decision-making could lead to accidents.

4.8 Undesirable effects
There is a potential for abuse with the use of BROMAZEPAM KIARA. Withdrawal symptoms (including convulsions, mental depression, insomnia and irritability) have occurred following abrupt cessation, especially in patients receiving large doses for prolonged periods.

Blood and lymphatic system disorders:
Unknown: Blood dyscrasias, including agranulocytosis, anaemia, neutropenia and thrombocytopenia.

Immune system disorders:
Unknown: Hypersensitivity, anaphylactic shock, angioedema.

Psychiatric disorders:
Less frequent: Depression of mood and affect, mental depression, disorientation or confusion* and lethargy. Paradoxical reactions such as restlessness, agitation, irritability, anger, nightmares, psychosis, inappropriate behaviour**, anterograde amnesia, memory impairment and acute hyper-excitability with rage may occur. If these occur, the medicine should be discontinued.
Unknown: Abnormal thinking including delusions (false beliefs that cannot be changed by facts), de-personalization (loss of sense of reality), disorientation, aggressive behaviour, hallucinations, euphoria, emotional disorder*, dependence**, drug abuse**, withdrawal syndrome**.

Nervous system disorders:
Frequent: Somnolence* (especially in elderly and debilitated patients and in patients receiving high doses), oversedation, dizziness or light headedness*, headache* and ataxia*.
Less frequent: Anxiety, nervousness, unusual excitement, seizures and tremor.
Unknown: Decreased alertness*.

Eye disorders:
Less frequent: Blurred vision or other changes in vision.
Unknown: Diplopia*.

Cardiac disorders:
Less frequent: Tachycardia and palpitations.
Unknown: Cardiac failure including cardiac arrest.

Vascular disorders:
Unknown: Hypotension.

Respiratory, thoracic and mediastinal disorders:
Less frequent: Increased bronchial secretions or excessive salivation.
Unknown: Respiratory depression.

Gastrointestinal disorders:
Less frequent: Abdominal or stomach cramps/pain, constipation, diarrhoea, dryness of mouth or increased thirst and nausea* or vomiting*.

Hepatobiliary disorders:
Unknown: Hepatic dysfunction (yellow skin and eyes).

Skin and subcutaneous tissue disorders:
Unknown: Rash, pruritus, urticaria.

Musculoskeletal and connective tissue disorders:
Less frequent: Muscle spasm.
Unknown: Dystonic extrapyramidal effects, muscle weakness*.

Renal and urinary disorders:
Less frequent: Urinary retention.

Reproductive system and breast disorders:
Less frequent: Changes in libido.

General disorders and administration site conditions:
Frequent: Slurred speech.
Unknown: Fatigue*.

Injury, poisoning and procedural complications:
Unknown: Falls, fractures***.

* *These phenomena occur predominantly at the start of therapy and usually disappear with repeated administration.*
** *See section 4.4 Warnings and precautions.*
****The risk of falls and fractures is increased in those taking concomitant sedatives (including alcoholic beverages) and in the elderly.*

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose
Symptoms:
Benzodiazepines commonly cause drowsiness, ataxia, dysarthria and nystagmus. Overdose of BROMAZEPAM KIARA is seldom life-threatening if the medicine is taken alone, but may lead to slurred speech areflexia, apnoea, hypotension, cardiorespiratory depression and coma. Coma, if it occurs, usually lasts a few hours, but it may be more protracted and cyclical, particularly in elderly patients. Benzodiazepine respiratory depressant effects are more serious in patients with respiratory disease.

Benzodiazepines increase the effects of other central nervous system depressants, including alcohol.

Treatment:
Monitor the patient's vital signs and institute supportive measures as indicated by the patient's clinical state. In particular, patients may require symptomatic treatment for cardiorespiratory effects or central nervous system effects.

If the patient is conscious (and not at risk of becoming obtundent or comatose), emesis should be induced mechanically.

Further absorption should be prevented using an appropriate method, e.g., treatment within 1 – 2 hours with activated charcoal. If activated charcoal is used, airway protection is imperative for drowsy patients.
In case of mixed ingestion, gastric lavage may be considered, however not as a routine measure.

If CNS depression is severe, consider the use of flumazenil, a benzodiazepine antagonist. This should only be administered under closely monitored conditions. It has a short half-life (about an hour), therefore patients administered flumazenil will require monitoring after its effects have worn off. Flumazenil is to be used with extreme caution in the presence of medicines that reduce seizure threshold (e.g., tricyclic antidepressants). Refer to the prescribing information for flumazenil, for further information on the correct use of this medicine.

5. PHARMACEUTICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacological classification: A 2.6 Tranquillisers
ATC code: N05BA08 Benzodiazepine derivatives

Mechanism of action:
Bromazepam, a benzodiazepine derivative has anxiolytic, sedative, muscle-relaxant and anti-convulsant properties.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients

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.

6.2 Incompatibilities
Not applicable.

6.3 Shelf Life
24 months.

6.4 Special precautions for storage
Store at or below 25 ºC and protect from light.
Keep blisters in the outer carton until required for use.
KEEP OUT OF THE REACH OF CHILDREN.

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

6.6 Special precautions for disposal
No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION
Kiara Health (Pty) Ltd
72 Steel Road
Spartan
Kempton Park, 1619
South Africa

8. REGISTRATION NUMBER
BROMAZEPAM 3 KIARA: S/2.6/149
BROMAZEPAM 6 KIARA: S/2.6/150

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION
21 March 1985

10. DATE OF REVISION OF TEXT
9 November 2021

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
72 Steel Road, Spartan
Kempton Park, 1619
South Africa

PATIENT INFORMATION LEAFLET
BROMAZEPAM 3 KIARA / BROMAZEPAM 6 KIARA

SCHEDULING STATUS: S5

BROMAZEPAM 3 KIARA (3 mg, tablets)
BROMAZEPAM 6 KIARA (6 mg, tablets)

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, Spartan
Kempton Park, 1619
South Africa

This leaflet was last revised on
9 November 2021

Registration Number
BROMAZEPAM 3 KIARA: S/2.6/149
BROMAZEPAM 6 KIARA: S/2.6/150

PASIËNTINLIGTINGSBLAADJIE
BROMAZEPAM 3 KIARA / BROMAZEPAM 6 KIARA

SKEDULERINGSTATUS: S5

BROMAZEPAM 3 KIARA (3 mg, tablette)
BROMAZEPAM 6 KIARA (6 mg, tablette)

Elke BROMAZEPAM 3 KIARA-tablet bevat suiker (laktose 100 mg).
Elke BROMAZEPAM 6 KIARA-tablet bevat suiker (laktose 100 mg).

Lees die hele blaadjie sorgvuldig voordat u begin om BROMAZEPAM KIARA te gebruik
- Hou hierdie blaadjie. U mag nodig kry om dit weer te lees.
- Indien u verdere vrae het, vra asseblief u dokter, apteker, verpleegsuster of ander gesondheidsorgverskaffer.
- BROMAZEPAM KIARA is vir u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit mag hulle skaad, selfs al is hulle simptome dieselfde as u simptome.

1. Wat BROMAZEPAM KIARA is en waarvoor dit gebruik word
- BROMAZEPAM KIARA bevat die aktiewe bestanddeel bromasepaam.
- Bromasepaam behoort aan 'n groep van medisyne genaamd bensodiasepiene.
- BROMAZEPAM KIARA word vir die behandeling van angsaanvalle gebruik.

2. Wat u nodig het om te weet voordat u BROMAZEPAM KIARA neem
Moenie BROMAZEPAM KIARA neem nie
- Indien u hipersensitief (allergies) vir bromasepaam of bensodiasepiene of enige van die ander bestanddele in BROMAZEPAM KIARA (gelys in afdeling 6) is.
- Indien u swanger is of borsvoed.
- Indien u aan 'n spiersiekte genaamd miastenie gravis ly.
- Indien u aan akute toehoekgloukoom (verhoogde oogdruk) ly.
- Indien u erge asemhalingsprobleme of 'n longsiekte het.
- Indien u 'n toestand genaamd 'slaapapneesindroom' het (waar u asemhaling ophou wanneer u besig is om te slaap).
- Indien u erge lewerprobleme het.
- Indien u die antiswammiddels itrakonasool of ketokonasool, om 'n swaminfeksie te behandel, gebruik.

Waarskuwings en voorsorgmaatreëls
Sê vir u dokter:
- Indien u aan 'n longsiekte ly en verminderde longkapasiteit het.
- Indien u aan ingekorte renale funksie (nierfunksie) of hepatiese funksie (lewerfunksie) ly.
- Indien u 'n geskiedenis van alkohol- of dwelmmisbruik het.
- Indien u aan depressie ly en antidepressante neem.
- Indien u soms selfdoodgedagtes het.
- Indien u medisyne genaamd opioïede (naloksoon, morfien en fentaniel) vir pynverligting gebruik.
- Indien dit voel asof BROMAZEPAM KIARA nie meer so goed soos vantevore werk nie (die effek mag na herhaalde gebruik oor 'n paar weke afneem).

Bejaarde pasiënte en verswakte pasiënte is meer vatbaar vir oorsedasie en respiratoriese onderdrukking.

Daar is 'n potensiaal vir misbruik en die ontwikkeling van fisiese en fisiologiese afhanklikheid, veral met verlengde gebruik en hoë dosisse.

Indien u enige van die volgende simptome ontwikkel, lig asseblief onmiddellik u dokter in:
Verlies aan die sin vir realiteit, rusteloos voel, geagiteerd of geïrriteerd voel, aggressief voel, woedebuie ervaar, nagmerries kry, verskerpte gehoor, gevoelloosheid en tinteling in die arms en bene, hipersensitiwiteit vir lig, geraas en fisiese kontak, hallusinasies (hoor, sien of voel dinge wat nie daar is nie), onvanpaste gedrag (bv. verlies van inhibisie en roekelose besluitneming) of epileptiese toevalle (stuipe). Hierdie simptome mag meer algemeen in kinders en in bejaardes voorkom.

Voor u BROMAZEPAM KIARA neem, maak seker dat dit vir u moontlik is om vir etlike ure ononderbroke te slaap; andersins mag u aan 'n toestand genaamd 'anterograde amnesie' ly – dit is 'n toestand waar dit moeilik is om nuwe herinneringe vas te lê. Dit mag ook tot ontoepaslike gedrag, soos verlies van inhibisie en roekelose besluitneming, lei.

Ander medisyne en BROMAZEPAM KIARA
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem (dit sluit alle aanvullende of tradisionele geneesmiddels in).

Lig u dokter of apteker in indien u tans die volgende gebruik:
- Antidepressante, antihistamiene (hooikoorsbehandeling) en antipsigotiese behandeling.
- Medisyne wat gebruik word om u te help slaap (bv. angsverligtende middels of kalmeermiddels).
- Sisapried en simetidien (behandeling gebruik vir gastro-intestinale siektes).
- Opioïed-analgetika (naloksoon, morfien en fentaniel).
- Karbamasepien (anti-epileptiese medisyne).
- Behandeling vir hoë bloeddruk (trimetafaan en kalsiumkanaalblokkers).
- Propranolol (gebruik om hoë bloeddruk, tremor en borskaspyn te behandel).
- Fluvoksamien (gebruik om obsessief-kompulsiewe steuring en angs te behandel).
- 'n Orale voorbehoedmiddel (die "pil").
- Medisyne wat gebruik word om infeksies, insluitende MIV, te behandel (byvoorbeeld protease-inhibeerders).
- Itrakonasool of ketokonasool (antiswammiddels) (sien **Moenie BROMAZEPAM KIARA neem nie**).

Gesamentlike gebruik van BROMAZEPAM KIARA en opioïede (sterk pynmedikasie, middels vir vervangingsterapie en sommige hoesmedisyne) verhoog die risiko vir lomerigheid, asemhalingsprobleme (respiratoriese onderdrukking) en koma en mag lewensdreigend wees. As gevolg hiervan moet gepaardgaande gebruik slegs oorweeg word wanneer ander behandelingsopsies nie moontlik is nie.

U dokter en apteker sal meer inligting hê oor medisyne waarmee u versigtig moet wees of wat u moet vermy terwyl u BROMAZEPAM KIARA neem.

BROMAZEPAM KIARA met kos en drankies en alkohol
Die gebruik van alkohol saam met BROMAZEPAM KIARA word nie aanbeveel nie.

Swangerskap, borsvoeding en fertiliteit
Indien u swanger is of borsvoed, dink dat u swanger mag wees of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u BROMAZEPAM KIARA neem.
BROMAZEPAM KIARA moenie tydens swangerskap gebruik word nie.
U moet dit óf vermy om BROMAZEPAM KIARA te neem terwyl u borsvoed óf u moet borsvoeding staak. Dit is nie bekend of BROMAZEPAM KIARA 'n ongebore baba kan beïnvloed of in borsmelk uitgeskei word nie.

Bestuur en die gebruik van masjinerie
Omsigtigheid word aanbeveel wanneer 'n motor bestuur, gevaarlike hoogtes geklim of gevaarlike masjinerie bedryf word. Die gebruik van BROMAZEPAM KIARA kan tot lomerigheid, geheueverlies, ingekorte besluitneming, ingekorte konsentrasie of ingekorte spierfunksie lei en dit mag weer ongelukke veroorsaak. Hierdie newe-effekte is meer waarskynlik met die aanvang van behandeling, wanneer die dosis vermeerder word, met gebrek aan slaap of met die gebruik van alkohol.

BROMAZEPAM KIARA bevat suiker (laktosemonohidraat)
BROMAZEPAM KIARA-tablette bevat 'n bestanddeel genaamd laktose (melksuiker). Indien u erge laktose-onverdraagsaamheid, galaktose-onverdraagsaamheid of glukose-galaktose-wanabsorpsie het, lig u dokter in voordat u BROMAZEPAM KIARA neem.

3. Hoe om BROMAZEPAM KIARA te neem
Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.
Neem BROMAZEPAM KIARA altyd presies soos wat u dokter of apteker u meegedeel het. Raadpleeg u dokter of apteker indien u onseker is.

Behandeling moet teen die laagste aanbevole dosis begin word.
Die maksimum dosis moenie oorskry word nie.
Die gewone dosis is 1,5 tot 3 mg drie keer per dag.

Ernstige gevalle, veral in die hospitaal:
6 tot 12 mg twee tot drie keer daagliks.

Hierdie hoeveelhede is gemiddelde aanbevelings en die dosis moet individueel bepaal word. Behandeling van buite-pasiënte begin oor die algemeen met die laagste dosis wat geleidelik, indien nodig, tot die optimale vlak vermeerder word. Na gelang van die vordering tydens terapie, kan die dosis gewoonlik geleidelik verlaag en dan gestaak word.

Duur van behandeling:
Behandeling moet so kort as moontlik wees. U moet gereeld geassesseer word en die behoefte aan voortgesette behandeling herevalueer word, veral wanneer u simptoomvry is. Die algehele duur van behandeling behoort oor die algemeen nie meer as 8 tot 12 weke te wees nie – insluitende 'n trapsgewyse afskaling.

Indien u meer BROMAZEPAM KIARA geneem het as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien u vergeet om BROMAZEPAM KIARA te neem
Moenie 'n dubbele dosis neem/ontvang om vir 'n vergete individuele dosis op te maak nie. Indien u sukkel om te onthou wanneer om u medisyne te gebruik, vra u apteker vir wenke.

Indien jy ophou om BROMAZEPAM KIARA te neem
Moenie ophou om u tablette te neem sonder om u dokter te raadpleeg nie. Die frekwensie waarteen BROMAZEPAM KIARA geneem word, moet stadig verminder (afgeskaal) word. Dit kan tot gemoedsveranderinge, angs, slaaploosheid en rusteloosheid lei.

4. Moontlike newe-effekte
BROMAZEPAM KIARA kan newe-effekte hê. Nie alle newe-effekte wat vir BROMAZEPAM KIARA gemeld is, is in hierdie blaadjie ingesluit nie. Sou u algemene gesondheid agteruitgaan of indien u enige ongunstige effekte ervaar terwyl u BROMAZEPAM KIARA neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om BROMAZEPAM KIARA te neem en spreek u dokter onmiddellik of gaan na die ongevalle-afdeling by u naaste hospitaal:
- Swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme met sluk of asemhaling mag veroorsaak.
- Dowwe visie of ander visieveranderinge.
- Stuipe (epileptiese toevalle).

Hierdie is almal baie ernstige newe-effekte. Indien u dit het, mag u 'n ernstige reaksie op BROMAZEPAM KIARA gehad het. U mag dringende mediese aandag of hospitalisasie benodig.

Indien enige van die volgende gebeur, hou op om BROMAZEPAM KIARA te neem en spreek u dokter onmiddellik of gaan na die ongevalle-afdeling by u naaste hospitaal:
- Geel vel of geel oë.
- Maagpyn met seerheid (teerheid) wanneer u aan die regter kant net onder u ribbes druk.
- 'n Gevoel van naarheid wat nie verklaarbaar is nie.
- Moegheid.
- 'n Gevoel dat u besig is om griep te kry.

Hierdie is almal ernstige newe-effekte. U mag dringende mediese aandag benodig.

Die volgende newe-effekte mag ondervind word:
Algemene newe-effekte sluit in:
- Lomerig of slaperig voel.
- Duiseligheid.
- Hoofpyn.
- Lighoofdigheid.
- Onbeholpenheid of onvastigheid.
- Slepende spraak.

Minder algemene newe-effekte sluit in:
- Gebrek aan geheue van gebeure wat plaasgevind het nadat BROMAZEPAM KIARA geneem is.
- Angs, geestelike depressie, irriteerbaarheid, senuweeagtigheid, ongewone opwinding, toevalle (stuipe) en tremor.
- Disoriëntasie of verwarring.
- Rusteloos, kwaad of geagiteerd wees of vol van woede voel.
- Nagmerries.
- Vreemde en ongewone gedagtes hê, dinge hoor of sien wat nie bestaan nie.
- 'n Verandering in u gedrag wat buite karakter is.
- Vinnige, bonsende of onreëlmatige hartklop.
- Meer slym in u longe as gewoonlik.
- Meer speeksel as gewoonlik.
- Buik- of maagkrampe/pyn, hardlywigheid, diarree, droogheid van die mond of vermeerderde dors en naarheid of braking.
- Spierspasma.
- Sukkel om water te passeer (urinering).
- Veranderinge in u seksdrang.

Die frekwensie van die volgende newe-effekte is onbekend:
- Onverklaarde bloeding en/of kneusing; verhoogde risiko vir infeksies, bv. kouekoors, koors, seerkeel, ongewone moegheid of swakheid, mondsere en bleek vel, wat die simptome van 'n toestand genaamd bloeddiskrasieë is.
- Valse oortuigings wat nie deur die feite verander kan word nie (abnormale denke).
- Verlies aan sin vir realiteit, disoriëntasie, aggressiewe gedrag, hallusinasies, valse sin van welstand, baie gelukkig voel (euforie), emosioneel voel.
- Verslaaf raak aan of afhanklik word van BROMAZEPAM KIARA.
- Onttrekkingsindroom (sien **Indien jy ophou om BROMAZEPAM KIARA te neem**).
- Minder waaksaam wees.
- Dubbelvisie (diplopie).
- Hartprobleme insluitende hartversaking (wat as uitasemheid, swelling van die enkels, hoes, moegheid en 'n hart wag jaag, gesien kan word) en hartarres.
- Lae bloeddruk.
- Asemhalingsprobleme (respiratoriese onderdrukking). Vroeë tekens sluit skielike raserige, moeisame en onreëlmatige asemhaling in. U vel mag blou word.
- Veluitslae, jeukende vel en rooiverkleuring van die vel.
- Ongekontroleerde bewegings van die liggaam, insluitende die oë.
- Swak spiere.
- Pasiënte wat BROMAZEPAM KIARA neem het 'n risiko om te val en bene te breek. Hierdie risiko is hoër in bejaardes en diegene wat ander kalmeermiddels (insluitende alkohol) gebruik.

Indien u enige newe-effekte opmerk wat nie in hierdie blaadjie genoem word nie, lig asseblief u dokter of apteker in.

Aanmelding van newe-effekte
Indien u newe-effekte kry, gesels met u dokter, apteker of verpleegsuster. U kan newe-effekte ook aan die SARGP via die "**6.04 Nadelige Middelreaksie-Aanmeldingsvorm**" rapporteer; dit kan aanlyn onder die SARGP se publikasies by https://www.sahpra.org.za/Publications/Index/8 gevind word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van BROMAZEPAM KIARA te voorsien.

5. Hoe om BROMAZEPAM KIARA te berg
Berg teen of benede 25 °C en beskerm teen lig.
BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.
Moenie die tablette na die vervaldatum wat op die stulpstroke en houers gedruk is, gebruik nie. Ontbinde produkte mag toksies wees.
Besorg alle ongebruikte medisyne aan u apteker terug.
Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) weggooi nie.
Hou die stulpstroke in die buitenste karton tot dit vir gebruik benodig word.

6. Inhoud van die pakkie en ander inligting
Wat BROMAZEPAM KIARA bevat
Elke BROMAZEPAM 3 KIARA-tablet bevat 3 mg bromasepaam.
Elke BROMAZEPAM 6 KIARA-tablet bevat 6 mg bromasepaam.

Onaktiewe bestanddele:
BROMAZEPAM 3 KIARA:
Laktose, mieliestysel, povidoon K30, gesuiwerde talk, magnesiumstearaat en Spectracol eritrosienlak.

BROMAZEPAM 6 KIARA:
Laktose, mieliestysel, povidoon K30, gesuiwerde talk, magnesiumstearaat en groenappel- diep kleurselpoeier.

Waarna BROMAZEPAM KIARA lyk en inhoud van die pakkie
BROMAZEPAM 3 KIARA:
Ronde, pienk, gevlekte, plat tablet, gekeep aan die een kant, 8 mm in deursnee.
BROMAZEPAM 6 KIARA:
Ronde, groen, gevlekte, plat tablet, gekeep aan die een kant, 8 mm in deursnee.

Voorsien in amberkleurige glasbottels, wit HDPE-sekuriteitshouers of stulpstroke van 30, 60, 100, 500 of 1000 tablette. Nie alle verpakkingsgroottes word bemark nie.

Houer van die Sertifikaat van Registrasie
Kiara Health (Pty) Ltd
72 Steel Road, Spartan
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South Africa

Hierdie blaadjie was laas hersien op
9 November 2021

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