Applicant/HCR	:	Umsebe Healthcare	V3 (25.06.2024)
Product name, strength and dosage form	:	ZENZIKET 1 mg/ml, solution for infusion	

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

ZENZIKET 1 mg/ml

Solution for infusion

Ketamine hydrochloride

Sugar free

Read all of this leaflet carefully before you are given ZENZIKET

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

What is in this leaflet

1. What ZENZIKET is and what it is used for

ZENZIKET belongs to a group of medicines called anaesthetics. When injected, it causes sedation, loss of mobility and will make you go to sleep and lose consciousness. It has powerful pain blocking properties. It acts on the brain, and the nerve pathways and networks within your brain.

ZENZIKET is used:

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Implemented: 25 June 2024

- For the induction of anaesthesia, or it may be used on its own or in combination with other anaesthetics, to maintain general anaesthesia.
- In children for the management of minor surgical and diagnostic procedures or procedures that require intense analgesia, such as changing burn dressings.

2. What you need to know before you are given ZENZIKET

ZENZIKET should not be given to you if you:

- Are hypersensitive (allergic) to ketamine hydrochloride or to any of the other ingredients of ZENZIKET (listed in section 6).
- Are suffering from any condition in which an increase of blood pressure may be harmful to you or have suffered in the past from a medical condition which may have been caused/made worse by an increase in blood pressure.
- Previously suffered a stroke.
- Have or recently had a serious head or brain injury.
- Have developed high blood pressure during pregnancy (where your blood pressure was previously normal) called eclampsia or pre-eclampsia.
- Have severe heart disease.
- Suffer from high pressure in your eye or have an object penetrating your eye.
- Are pregnant or breastfeeding.

Warnings and precautions

Tell your doctor or healthcare professional before being given ZENZIKET if you:

- Recently had a heart attack or suffer from any heart disease or condition.
- Suffer from increased pressure on your brain.
- Have increased pressure in the eye (glaucoma).
- Have an eye injury, where the eye has been perforated (pierced).
- Drink large amounts of alcohol.
- Have problems with your liver or kidneys.
- Are dehydrated.

- Have a history of or have current mental health problems.
- Have an inherited disease that affects the blood, called porphyria.
- Have or ever had seizures (fits).
- Are receiving treatment for your thyroid gland.
- Have a chest infection or problems breathing.
- Have had any injury of your head or abnormal growth in the brain.
- Have a history of drug abuse or addiction.

Some people have hallucinations, vivid dreams, nightmares, feel ill at ease, confused, anxious or behave irrationally while recovering from anaesthesia with ZENZIKET. These side effects are collectively known as an “emergence reaction”. You will be allowed to recover from the anaesthetic in a quiet place, which helps to prevent the reaction (see section “Possible side effects”).

If you are receiving ZENZIKET on a long-term basis, you may experience bladder and liver complications. Speak to your doctor, since ZENZIKET is not intended for long-term use.

Children and adolescents

ZENZIKET must not be used in children aged less than 3 months due to potential respiratory complications.

Other medicines and ZENZIKET

Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines).

Some medicines and ZENZIKET may interfere with each other. These include:

- Inhalational anaesthetics, such as ether or halothane.
- Barbiturates, such as phenobarbital (used to treat epilepsy and anxiety) and thiopental (an anaesthetic agent) or narcotic analgesics (strong painkillers) such as morphine or fentanyl.
- Muscle relaxants, such as atracurium or tubocurarine.

- Other central nervous system (CNS) depressants, such as ethanol (alcohol), chlorpromazine (used to treat mental illness), chlorphenamine (used for the treatment of allergies).
- Tranquillisers or sedatives (sleeping tablets and tablets used to treat depression), such as diazepam or zopiclone.
- Antihypertensive medicines (medicines to treat high blood pressure), such as atenolol.
- Bronchodilators (medicines which help breathing), such as theophylline or aminophylline.
- Thyroid hormones used to treat thyroid gland conditions, such as thyroxine.
- Medicines called sympathomimetics, which include adrenaline (epinephrine) and noradrenaline (norepinephrine).
- Vasopressin (a hormone with multiple uses, including the treatment of diabetes, to increase blood pressure, to control bleeding).
- Ergometrine (used during or after childbirth to reduce bleeding).

Tell your doctor if you are taking any of the above medicines.

Ketamine with food and drink

It is normal not to eat or drink for at least six hours before an operation; therefore, ZENZIKET is usually given when your stomach is empty. If in an emergency this is not possible and ZENZIKET may still be used.

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 being given this medicine.

Safety in pregnancy and breastfeeding has not been established. ZENZIKET should not be given to you if you are pregnant or breastfeeding.

Driving and using machines

Caution should be taken when driving or operating machines after having received ZENZIKET. You

should not drive or operate machines for at least 24 hours after you have been given ZENZIKET, as it may make you sleepy or dizzy.

You should not make important decisions nor take alcohol for at least 24 hours after receiving ZENZIKET.

ZENZIKET contains sodium

ZENZIKET contains less than 1 mmol sodium (23 mg) per ml, that is to say ZENZIKET is essentially 'sodium-free'.

3. How you will be given ZENZIKET

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

You will not be expected to give yourself ZENZIKET. It will be given to you by a person who is qualified to do so.

Your doctor will decide what your dose is and for how long you will receive ZENZIKET. This will vary from patient to patient. It will depend on your condition and other factors, such as your physical condition, weight, age, as well as other medicines that you are taking at the time or afterwards.

ZENZIKET is given as a slow intravenous infusion directly into the vein until surgery is complete.

If you are given more ZENZIKET than you should

Since a health care provider will administer ZENZIKET, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

ZENZIKET can have side effects.

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

provider for advice.

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Severe rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZENZIKET. 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:

- While recovering from anaesthesia (these are collectively known as an “emergence reaction”): hallucinations (which may include flashbacks or floating sensation), vivid dreams, nightmares, feeling ill at ease, confused and irrational behaviour (see section “Warnings and precautions”).
- Increased pressure in the skull, which will present as a bad headache.
- Unusual eye movements, increased muscle tone and muscle twitches (which may resemble fits or convulsions).
- Double vision or involuntary rapid eye movement.
- Raised pressure in the eyes.
- Increased blood pressure and increased pulse rate.
- Slowing of heart rate, changes in heart rhythm.
- Breathing faster, or more slowly, narrowing of the voice box leading to difficulty in breathing, stop breathing while you are asleep (apnoea).
- Effect on the reflexes which keep your airways clear, resulting in temporary inability to breathe.
- Medicine-induced liver injury (see section “Warnings and precautions”). You may experience symptoms such as loss of appetite, nausea, vomiting, fever, weakness, abdominal pain, and

yellowing of the eyes and skin.

- Measle-like skin rash.
- Inflammation of the bladder and/or pain when urinating. The appearance of blood may also occur.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea and vomiting.

Less frequent side effects:

- Feeling anxious.
- Drifting in and out of consciousness (with a feeling of confusion and hallucinations), flashbacks, feeling uneasy, sleeplessness, feeling disorientated.
- Feeling dizzy (vertigo).
- Lowering of blood pressure.
- Loss of appetite and weight (anorexia).
- Drooling.
- Pain, inflammation of the skin or rash at the site of injection.

Frequency unknown:

- Increase in the production of tears.
- Temporary skin rashes.

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 ZENZIKET.

5. How to store ZENZIKET

Store at or below 30 °C. Do not refrigerate or freeze.

Store in original package in order to protect from light.

Keep out of the sight and reach of children.

Do not use after the expiry date printed on the carton.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What ZENZIKET contains

The active substance is ketamine (as ketamine hydrochloride).

Each 1 ml of the solution for infusion contains ketamine hydrochloride equivalent to 1 mg ketamine base.

The other ingredients are sodium chloride and water for injections.

What ZENZIKET looks like and contents of the pack

ZENZIKET is a clear, colourless solution.

ZENZIKET is presented in 100 ml polypropylene infusion bags equipped with an infusion port and an adjunction port. The adjunction port is closed with a bromobutyl stopper and is sealed with an aluminium/plastic flip-off cap. Bags are packed into outer cardboard cartons in pack sizes of 10 bags per carton.

Holder of Certificate of Registration

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South Africa

Name of Manufacturer: Sintetica SA

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Access to the corresponding Professional Information

25 June 2025

NAMIBIA:

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