Approved Patient Information Leaflet for Ketamine Fresenius

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

KETAMINE 10 mg/1 ml, 50 mg/1 ml and 100 mg/1 ml FRESENIUS

Solution for injection or infusion

Ketamine hydrochloride

Sugar free

Read all of this leaflet carefully before you receive KETAMINE FRESENIUS:

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

What is in this leaflet:

1. What **KETAMINE FRESENIUS** is and what it is used for
2. What you need to know before you receive **KETAMINE FRESENIUS**
3. How to receive **KETAMINE FRESENIUS**
4. Possible side effects
5. How to store **KETAMINE FRESENIUS**
6. Contents of the pack and other information

1. What KETAMINE FRESENIUS is and what it is used for

KETAMINE FRESENIUS 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.

KETAMINE FRESENIUS is used:

- 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 receive KETAMINE FRESENIUS

KETAMINE FRESENIUS should not be given to you if you:

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

Warnings and precautions:

Tell your doctor before given **KETAMINE FRESENIUS** if you:

- Suffer from convulsions, hallucinations, or suffer from any form of psychiatric disease.
- Have epilepsy.
- Have porphyria (inherited blood disorder that can cause nerve or skin problems).
- Suffer from increased pressure on your brain.
- Have kidney or liver disease.
- Drink alcohol.
- Have a history of drug abuse or addiction.
- Have a chest infection or problems breathing.
- Are receiving treatment for your thyroid gland.
- Have had an injury to your head or abnormal growth in the brain.

Take special care with **KETAMINE FRESENIUS**:

- As **KETAMINE FRESENIUS** is administered during surgery, you will not be aware of the side effects if they do occur. You will be closely monitored during the post-operative recovery period so that any side effects that do occur can be treated immediately.
- Some people have hallucinations, vivid dreams, nightmares, feel ill at ease, confused, anxious or behave irrationally while recovering from anaesthesia with **KETAMINE FRESENIUS**. These side effects are collectively known as an “emergence reaction”. You will be allowed to recover from the anaesthetic in a quiet place and this helps to prevent the reaction (see section “Possible side effects”).
- If you are receiving **KETAMINE FRESENIUS** on a long-term basis, you may experience bladder and liver complications. Speak to your doctor, since Ketamine Fresenius is not intended for long-term use.

Other medicines and KETAMINE FRESENIUS:

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

Some medicines and **KETAMINE FRESENIUS** may interfere with each other. These include:

- Barbiturates, such as phenobarbital and thiopental or narcotic analgesics such as morphine or fentanyl.
- Ergometrine.
- Tranquillisers or sedatives, such as diazepam or zopiclone.
- Sympathomimetics (such as adrenaline [epinephrine] or noradrenaline [norepinephrine]) or vasopressin.
- Other central nervous system (CNS) depressants, such as ethanol or chlorpromazine, chlorphenamine.
- Inhalational anaesthetics, such as ether or halothane.
- Muscle relaxants, such as atracurium or tubocurarine.
- Thyroid hormones, such as thyroxine.
- Antihypertensive medicines, such as atenolol.
- Bronchodilators, such as theophylline or aminophylline.

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

KETAMINE FRESENIUS with food and drink:

There are no known interactions between **KETAMINE FRESENIUS**, food and drink.

Pregnancy and breastfeeding:

Safety in pregnancy and breastfeeding has not been established.

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 receiving **KETAMINE FRESENIUS.**

Driving and using machines:

Caution should be taken when driving or operating machines following treatment with **KETAMINE FRESENIUS**. You should not drive or operate machines in the first 24 hours after you have been given **KETAMINE FRESENIUS.**

KETAMINE FRESENIUS can affect your ability to drive as it may make you sleepy or dizzy.

You should not make important decisions nor take alcohol for 24 hours after receiving **KETAMINE FRESENIUS.**

KETAMINE 10 mg/1 ml FRESENIUS contains sodium chloride:

KETAMINE 10 mg/1 ml FRESENIUS contains less than 1 mmol sodium (23 mg) sodium per vial, that is to say **KETAMINE 10 mg/1 ml FRESENIUS** is essentially sodium free.

3. How to receive KETAMINE FRESENIUS

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

You will not be expected to give yourself **KETAMINE FRESENIUS**. 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 **KETAMINE FRESENIUS**. 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.

KETAMINE FRESENIUS is given as a single dose injection or on a continuous basis for the duration of the operation.

KETAMINE FRESENIUS injection is administered either

- directly into the muscle (intramuscular),
- as a slow injection directly into the vein (intravenous) over 60 seconds,
- or a slow intravenous infusion directly into the vein until surgery is complete.

Ketamine Fresenius will not be administered to you as an intrathecal injection (via the spinal canal).

You should not eat or drink for at least six hours before an operation; therefore, **KETAMINE FRESENIUS** is usually given when your stomach is empty. If in an emergency this is not possible, **KETAMINE FRESENIUS** may still be used.

If you receive more KETAMINE FRESENIUS than you should:

Since a health care professional will administer **KETAMINE FRESENIUS**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive KETAMINE FRESENIUS:

Since a health care provider will administer **KETAMINE FRESENIUS**, it is unlikely that the dose will be missed.

4. Possible side effects

KETAMINE FRESENIUS can have side effects.

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

If any of the following happens, stop receiving **KETAMINE FRESENIUS** 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 **KETAMINE FRESENIUS**. 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, anxious and irrational behaviour (see section “Warnings and

precautions").

- 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.
- Measle-like skin rash.
- 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.
- Inflammation of the bladder and/or pain when urinating. The appearance of blood may also occur.
- Medicine-induced liver injury (see section "Warnings and precautions"). You may experience symptoms such as loss of appetite, nausea, vomiting, fever, weakness and abdominal pain.

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Nausea and vomiting.

The following side effects have been reported less frequently:

- Loss of appetite. Feeling anxious.
- Lowering of blood pressure.
- Pain, inflammation of the skin or rash at the site of injection.
- Drooling.
- Abdominal pain, including inflamed and irritated pancreas.

Side effects where the frequency is unknown:

- Increase in the production of tears.
- Abnormal results of liver function test.

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 or pharmacist. 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 **KETAMINE FRESENIUS**.

Health care providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com, and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store KETAMINE FRESENIUS

- **KETAMINE FRESENIUS** will be stored in the pharmacy or in the hospital wards.
- The injection should be stored at or below 30 °C.
- STORE ALL MEDICINE OUT OF 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 KETAMINE FRESENIUS contains:

The active ingredient is ketamine hydrochloride.

Each 1 ml solution contains ketamine hydrochloride equivalent to 10 mg, 50 mg or 100 mg ketamine, respectively.

The other ingredients are water for injection, benzethonium chloride (as preservative), sodium hydroxide (for pH adjustment) and hydrochloric acid (for pH-adjustment).

KETAMINE 10 mg/1 ml FRESENIUS also contains sodium chloride, to make the solution isotonic (having the same concentration of solutes as the blood).

What KETAMINE FRESENIUS looks like and contents of the pack:

A clear, colourless solution in amber vials.

KETAMINE 10 mg/1 ml FRESENIUS: 20 ml amber Type I glass vials, sealed with a chlorobutyl rubber stopper and crimped with an aluminium seal, containing 20 ml of solution as 10 mg ketamine per ml.

KETAMINE 50 mg/1 ml FRESENIUS: 10 ml amber Type I glass vials sealed with a chlorobutyl rubber stopper and crimped with an aluminium seal, containing 10 ml of solution as 50 mg ketamine per ml.

KETAMINE 100 mg/1 ml FRESENIUS: 10 ml amber Type I glass vials sealed with a chlorobutyl rubber stopper and crimped with an aluminium seal, containing 10 ml of solution as 100 mg ketamine per ml.

Pack sizes: packs of fives, tens or singles per outer carton.

Not all pack sizes may be marketed.

Holder of certificate of registration and manufacturer:

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten, 6020

Gqeberha

South Africa

Tel.: 041 403 1600

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