

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **KETAM**

(Ketamine Injection BP, 50 mg/ml)

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

#### **In this leaflet:**

1. Name of Product
2. Description of Product
3. What is in the medicine ?
4. Strength of the Medicine
5. What is this Medicine used for ?
6. How much and how often should you use this Medicine ?
7. When should you not take this Medicine ?
8. Undesirable Effects
9. What other medicine or food should be avoided whilst taking this medicine ?
10. What should you do if you miss a dose ?
11. How should you keep this Medicine ?
12. Sign & Symptoms of over dosage
13. What to do when you have taken more than the recommended dosage ?
14. Care that should be taken when taking this Medicine ?
15. When should you consult your doctor ?
16. Name/logo of Marketing Authorization Holder

### **1. Name of Product**

Brand Name: KETAM

Generic Name: Ketamine Hydrochloride Injection BP, 50mg/ml

### **2. Description of Product**

Ketamine is a clear, colourless solution.

### **3. What is in the medicine ?**

#### **Composition :**

Each ml contains

Ketamine Hydrochloride BP equivalent to Ketamine 50 mg

Benzalkonium Chloride solution BP 0.02 % W/V

Water for injections BP q.s

### **4. Strength of the Medicine**

50mg/ml

### **5. What is this Medicine used for ?**

Ketam is recommended:as a sole anesthetic agent for diagnostics and surgical procedure that do not require skeletal muscle relaxation.ketam is best suited for short procedure but it can be used with additional doses for longer procedure.

For the induction of anesthesia prior to the administration of other general anesthetic agent.

To supplement low potency agents,such as nitrous oxide.

### **6. How much and how often should you use this Medicine?**

#### **How much is given**

For intravenous infusion, intravenous injection or intramuscular injection.

#### **Intravenous Infusion**

A solution containing 1 mg/ml of ketamine in dextrose 5% or sodium chloride 0.9% is suitable for administration by infusion.

### **General Anaesthesia Induction**

An infusion corresponding to 0.5 – 2 mg/kg as total induction dose.

### **Intravenous Route**

The initial dose of Ketamine administered intravenously may range from 1 mg/kg to 4.5mg/kg (in terms of ketamine base). The average amount required to produce 5 to 10 minutes of surgical anaesthesia has been 2.0 mg/kg. It is recommended that intravenous administration be accomplished slowly (over a period of 60 seconds). More rapid administration may result in respiratory depression and enhanced pressor response.

### **Intramuscular Route**

The initial dose of Ketamine administered intramuscularly may range from 6.5 mg/kg to 13 mg/kg (in terms of ketamine base). A low initial intramuscular dose of 4 mg/kg has been used in diagnostic manoeuvres and procedures not involving intensely painful stimuli. A dose of 10 mg/kg will usually produce 12 to 25 minutes of surgical anaesthesia.

## **7. When should you not take this Medicine ?**

Ketamine should not be administered to

- if you are allergic to ketamine hydrochloride or any of the other ingredients of this medicine.
- if you are suffering from any condition in which an increase in 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
- if you have been pregnant and during your pregnancy you have suffered from a condition called eclampsia or pre-eclampsia which causes an increase in your blood pressure
- if you have recently suffered a stroke or serious head or brain injury
- if you have severe heart disease

- if you are pregnant, trying to become pregnant or breast-feeding. However, Ketamine may safely be used in caesarean section surgery

## **8. Undesirable Effects**

### **Cardiovascular :**

Temporary elevation of blood pressure and pulse rate is frequently observed following administration of Ketamine hydrochloride. However hypotension and bradycardia have been reported. Arrhythmia has also occurred.

### **Respiration :**

Depression of respiration or apnoea may occur following rapid intravenous administration of high doses of Ketamine Hydrochloride.

### **Ocular :**

A slight elevation in intraocular pressure may also occur.

### **Psychological:**

During recovery from anesthesia the patient may experience delirium characterized by vivid dreams (Pleasant and Unpleasant), with or without psychomotor activity. Manifested by confusion and irrational behaviour.

### **Neurological:**

In some patient enhanced skeletal muscle tone may be manifested by tonic and clonic movements sometimes resembling seizures. Gastro intentional : Anorexia, nausea and vomiting have been observed. However these are minimal and not usually severe.

## **9. What other medicine or food should be avoided whilst taking this medicine ?**

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

## **10. What should you do if you miss a dose ?**

If you forget to take KETAM consult your doctor, health care provider or pharmacist. Do not use a double dose to make up for a forgotten dose.

### **11. How should you keep this Medicine?**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry dates refers to the last day of that month. Your pharmacist will check this before the injection is given. Do not freeze. This medicinal product does not require any special storage conditions. Store in the original container in order to protect from light.

### **12. Sign & Symptoms of over dosage**

Respiratory depression can result from an overdosage of Ketamine hydrochloride. Supportive Ventilation should be employed. Ketamine Hydrochloride has a wide margin of safety : Several instances of unintentional administration of overdoses of Ketamine Hydrochloride (upto 10 times that usually required) have been followed by prolonged but complete recovery.

### **13. What to do when you have taken more than the recommended dosage ?**

If you are given more Ketamine than you should you may experience breathing difficulties. Your doctor or nurse may provide you with equipment to help you breathe. If you have any further questions on the use of this medicine, ask your doctor or nurse.

### **14. Care that should be taken when taking this Medicine ?**

Talk to your doctor or nurse before using Ketamine if you:

- Drink large amounts of alcohol
- Have a history of drug abuse or addiction
- Have a history of or have current mental health problems
- Have a chest infection or problems breathing
- Have problems with your liver
- Have increased pressure in the eye (glaucoma)
- Have an inherited disease that affects the blood (porphyria)
- Have ever had seizures

- Are receiving treatment for your thyroid gland
- Have had any injury to your head or abnormal growth in the brain

If before your operation the pressure in your spinal cord is raised, your anaesthetist will pay special attention to this during the operation. oleate which are considered as safe.

### **15. When should you consult your doctor?**

Tell your doctor if

- you are pregnant or intend to become pregnant
- you are breast-feeding or plan to breast-feed
- you are suffering form prostate problem
- you have narrow angle glaucoma, megacolon or myasthenia gravis
- you have a very fast heart rate or other heart problem
- you have reflux esophagitis or ulcerative colitis
- you are hypersensitive or allergic to hyoscine butylbromide.
- you are taking antidepressants, major tranquilizers, antihistamines, dopamine antagonist (e.g metoclopramide) or medicines to treat heart problem
- you have sudden or severe abdominal pain along with symptoms such as fever, nausea, vomiting, blood in stool or low blood pressure contact your doctor immediately.

### **16. Name/logo of Marketing Authorization Holder**



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