

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

### **KETAMAX 50**

#### **Ketamine Hydrochloride Injection USP, 50 mg/mL**

**Read all of this leaflet carefully before you start using 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, health care provider or pharmacist.

#### **In this leaflet**

- a) What KETAMAX 50 is and what it is used for
- b) Before you use KETAMAX 50
- c) How to use KETAMAX 50
- d) Possible side effects
- e) How to store KETAMAX 50
- f) Further information

#### **a. What KETAMAX 50 is and what it is used for?**

- KETAMAX 50 is used as an anaesthetic agent for diagnostic and surgical procedures. When used by intravenous or intramuscular injection, KETAMAX 50 is best suited for short procedures. With additional doses, or by intravenous infusion, KETAMAX 50 can be used for longer procedures. If skeletal muscle relaxation is desired, a muscle relaxant should be used and respiration should be supported.
- For the induction of anaesthesia prior to the administration of other general anaesthetic agents.
- To supplement other anaesthetic agents.

**b. Before you use KETAMAX 50**

• **Do not use KETAMAX 50**

- If you are allergic (hypersensitive) to KETAMAX 50 or any other ingredients of KETAMAX 50.
- 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 severe heart disease.
- If you are pregnant, trying to become pregnant or breast-feeding.

• **Take special care with KETAMAX 50**

Talk to your doctor or nurse before receiving KETAMAX 50 if you

- drink large amounts of alcohol;
- have a history of drug abuse or addiction;
- 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);
- are receiving treatment for your thyroid gland;
- have had any injury of your head or abnormal growth in the brain;
- have ever had seizures (fits);
- have a history of or have current mental health problems

• **Taking other medicines**

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Ketamax 50 is usually given together with other medicines during surgery.

- Tell your doctor if you are taking barbiturates or narcotics (morphine-like drugs) since use with Ketamax 50 may slow your recovery from anaesthesia. Ketamax 50 may also decrease the effect of thiopental, a sedative medicine (barbiturate).

- Ketamax 50 may increase the effects of atracurium and tubocurarine (medicines that cause muscle relaxation) which may lead to serious breathing difficulties.
- When halogenated anaesthetics (medicines typically inhaled as part of general anaesthesia) are given at the same time as Ketamax 50, it may:
  - cause the effect of Ketamax 50 to last longer, and therefore delay recovery from anaesthesia.
  - increase the risk of developing a slow heart rate (bradycardia), low blood pressure (hypotension), or a reduced ability of the heart to function (decreased cardiac output).
- Ketamax 50 affects the central nervous system (CNS). When Ketamax 50 is given at the same time as alcohol or medicines which affect the CNS, the effect may be additive and may lead to the development of potentially fatal breathing difficulties. Doses of Ketamax 50 may therefore need to be reduced when given at the same time as other CNS-affecting medicines, medicines which include:
  - phenothiazines (medicines like chlorpromazine used to treat psychiatric disorders).
  - sedating antihistamines (medicines like chlorphenamine which have a sedative effect and are used to treat allergic reactions).
  - anxiolytics, sedatives and hypnotics (medicines such as benzodiazepines (e.g. diazepam) and 'Z-drugs' (e.g. zolpidem) which can be used to provide a calming effect, to induce drowsiness and aid sleep).
  - barbiturates (e.g. phenobarbital) used to control epilepsy.
- When Ketamax 50 is given at the same time as thyroid hormones (medicines like thyroxine), there is an increased risk of the development of high blood pressure (hypertension) and a fast heart rate (tachycardia).
- When Ketamax 50 is given at the same time as medicines which lower blood pressure (antihypertensive agents), there is an increased risk of the development of low blood pressure (hypotension).
- Ketamax 50 is broken down (metabolised) in the body mainly in the liver by a particular enzyme (CYP3A4 enzyme). When Ketamax 50 is given at the same

time as other medicines which affect the activity of this enzyme, the dose of Ketamax 50 may need to be changed to achieve the desired clinical effect.

- Diazepam can increase the effects of Ketamax 50 so dose adjustments may be needed.
- Using sympathomimetics (for example adrenaline or noradrenaline) or vasopressin with Ketamax 50 may lead to an increase in blood pressure and heart rate.
- Using Ketamax 50 with ergometrine may lead to an increase in blood pressure.
- Using Ketamax 50 with theophylline or aminophylline may lead to an increased likelihood of seizures.
- **Taking Ketamax 50 with food and drink**
- It is normal not to eat or drink for at least six hours before an operation; therefore Ketamax 50 is usually given when your stomach is empty.
- **Pregnancy and breast-feeding**
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before being given this medicine.
- **Driving and using machine**
- Caution should be taken when driving or operating machines following treatment with Ketamine. You should not drive or operate machines in the first 24 hours after your operation. This medicine can impair cognitive function and can affect a your ability to drive safely. When taking this medicine, you should be know:
  - The medicine is likely to affect your ability to drive
  - Do not drive until you know how the medicine affects you
- Important information about some of the ingredients of Ketamax 50
  - Not Applicable

**c. How to use KETAMAX 50**

- **How to take KETAMAX 50**
  - Your doctor will explain precisely how much Ketamax 50 you will be given, how often and for how long.

- Except in an emergency, Ketamax 50 should only be used in hospitals by experienced anaesthetists with resuscitation equipment available;
- Before your operation you will be usually given a medicine such as atropine or hyoscine to dry up your secretions (body fluids like saliva and tears) and another medicine called a benzodiazepine. The benzodiazepine will help you to relax and help to prevent a side effect known as “emergence reaction”;
- The dose of Ketamax 50 depends on its use and varies from person to person. When injected directly into a vein at a dose of 2 mg for every kg of your bodyweight, Ketamax 50 produces unconsciousness within 30 seconds and it lasts for 5 to 10 minutes. Because it works so quickly, it is important that you are lying down, or supported in some other way when the medicine is given to you. When Ketamine is injected into a muscle, at a dose of 10 mg for every kg of bodyweight, it takes longer to work (3 to 4 minutes) but lasts for 12 to 25 minutes;
- Your anaesthetist will then keep you anaesthetised with either:
  - another anaesthetic;
  - more Ketamax 50 given to you by an injection into a muscle or vein, or in a drip (infusion);
  - Ketamax 50 together with another anaesthetic.
- When it is injected directly into a vein, Ketamax 50 is given over at least a minute, so that it does not slow down your breathing too much. If your breathing is too slow, the doctor can help you mechanically;
- While you are anaesthetised, your anaesthetist will watch over you constantly, paying particular attention to your breathing, airways, reflexes, the degree of anaesthesia and the condition of your heart. You should not be discharged from the hospital until you have completely recovered from the anaesthetic. If you are discharged on the same day as the operation, you should be accompanied by another adult (see also the section on ‘Driving and using machines’).
- **If you take more KETAMAX 50 than you should**
  - experience breathing difficulties. In such case, your doctor or nurse may need to provide you with an equipment to help you breathe.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

- **If you forget to take KETAMAX 50**
  - Not Applicable
- **If you stop taking KETAMAX 50**
  - Not Applicable

**d. Possible side effects**

- Like all medicines, this medicine can cause side effects, although not everybody gets them.
- Tell your doctor immediately if you notice pain, inflammation of the skin or rash at the injection site. Ketamax 50 can sometimes cause allergic symptoms ('anaphylaxis') such as breathing problems, swelling and rash.
- Some people have hallucinations, vivid dreams, and nightmares, feel uneasy, confused, anxious or behave irrationally while recovering from anaesthesia with Ketamax 50. 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 c under 'How Ketamax 50 is use').
- Common side effects (may affect up to 1 in 10 people):
  - while recovering from anaesthesia: hallucinations (which may include flashbacks or floating sensation), vivid dreams, nightmares, feeling uneasy, confused, anxious and irrational behaviour (these side effects are collectively known as an 'emergence reaction');
  - unusual eye movements, increased muscle tone and muscle twitches (which may resemble 'fits' or convulsions);
  - double vision;
  - increased blood pressure and increased pulse rate;
  - breathing more quickly;
  - nausea, vomiting;
  - skin inflammation/rash.
- Uncommon side effects (may affect up to 1 in 100 people):
  - loss of appetite, feeling anxious;
  - slowing of heart rate, changes in heart rhythm;

- lowering of blood pressure;
- breathing more slowly, narrowing of the voice-box leading to difficulty in breathing;
- pain, inflammation of the skin or rash at the injection site.
- Rare side effects (may affect up to 1 in 1,000 people):
  - allergic symptoms ('anaphylaxis') such as breathing problems, swelling and rash;
  - drifting in and out of consciousness (with a feeling of confusion and hallucinations), flashbacks, feeling uneasy, sleeplessness, feeling disorientated;
  - affect on the reflexes which keep your airways clear, resulting in temporary inability to breathe;
  - increase in salivation;
  - inflammation of the bladder and/or pain when urinating ('cystitis'). The appearance of blood in the urine may also occur.
- Side effects where the occurrence is not known:
  - raised pressure in the eyes;
  - abnormal results in liver function tests

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 pharmacist.

**e. How to store KETAMAX 50**

- Keep 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.
- This medicinal product does not require any special storage conditions. Store in the original container in order to protect from light.

**f. Further information.**

- **What KETAMAX 50 contains?**
  - The active substance is ketamine hydrochloride. Each ml solution contains 50 mg of ketamine;
    - The other ingredients (excipients) are water for injections and a preservative (benzethonium chloride).

- **What KETAMAX 50 looks like and contents of the pack**
  - KETAMAX 50 (Ketamine Hydrochloride Injection USP 50 mg/ml) is available in 10 ml multidose vial.
- **Name and full physical address of Marketing Authorization Holder and Manufacturing site:**
  - *Marketing Authorization Holder*

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