



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
KETAMINE INJECTION
Ketamine Hydrochloride 50mg/ml

Read this leaflet carefully before you start taking this medicine.

- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. 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 become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

In this leaflet:

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

1. WHAT KETAMINE INJECTION IS AND WHAT IT IS USED FOR

Ketamine Hydrochloride is used in both routine and emergency surgery. Ketamine Hydrochloride is used in adults, the elderly and children. Ketamine Hydrochloride can be given alone or in combination with other anaesthetic agents.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE KETAMINE INJECTION

Do not use Ketamine Injection:

- 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 Hydrochloride may safely be used in caesarean section surgery or vaginal delivery.

Warnings and precautions

Talk to your doctor or nurse before using Ketamine Hydrochloride 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 difficulties breathing.
- Have problems with your liver.
- Have increased pressure in the eye (glaucoma).



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- 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.

Other medicines and Ketamine Hydrochloride

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

- Ketamine Hydrochloride is usually given together with other medicines during surgery.
- When used for an operation on the chest or abdominal organs, Ketamine Hydrochloride is usually combined with a pain-killer.
- Tell your doctor if you are taking barbiturates or narcotics (morphine-like drugs) since use with Ketamine Hydrochloride may slow your recovery from anaesthesia. Ketamine Hydrochloride may also decrease the effect of thiopental, a sedative medicine (barbiturate).
- Ketamine Hydrochloride may increase the effects of atracurium and tubocurarine (medicines that cause muscle relaxation) which may lead to serious breathing difficulties.

Take special care with Ketamine Injection

Check with your doctor before taking Ketamine Injection:

- If you have heart, liver or kidney problems. This is because your doctor may need to adjust the dose of Ketamine Injection
- If you have epilepsy.
- If you have been told that you have decreased volume of blood (hypovolaemia).
- You have accumulation of fluid around the lungs
- You are elderly or in poor general health
- You are in the late stages of pregnancy
- You suffer from blood poisoning (septicaemia).
- In children aged less than 12 years safety of taking Ketamine Hydrochloride in order to numb parts of the body during surgery has not been established. The use of ketamine injection is not established in children less than 1 year of age.
- When halogenated anaesthetics (medicines typically inhaled as part of general anaesthesia) are given at the same time as Ketamine Hydrochloride, it may:
 - Cause the effect of Ketamine Hydrochloride 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).
- Ketamine Hydrochloride affects the central nervous system (CNS). When Ketamine



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Hydrochloride 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 Ketamine Hydrochloride 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 Ketamine Hydrochloride 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 Ketamine Hydrochloride 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).
 - Ketamine Hydrochloride is broken down (metabolised) in the body mainly in the liver by a particular enzyme (CYP3A4 enzyme). When Ketamine Hydrochloride is given at the same time as other medicines which affect the activity of this enzyme, the dose of Ketamine Hydrochloride may need to be changed to achieve the desired clinical effect.
 - Diazepam can increase the effects of Ketamine Hydrochloride so dose adjustments may be needed.
 - Using sympathomimetics (for example adrenaline or noradrenaline) or vasopressin with Ketamine Hydrochloride may lead to an increase in blood pressure and heart rate.
 - Using Ketamine Hydrochloride with ergometrine may lead to an increase in blood pressure.
 - Using Ketamine Hydrochloride with theophylline or aminophylline may lead to an increased likelihood of seizures.

If you are not sure if any of the above applies to you, talk to your doctor before you are given Ketamine Injection.

Ketamine Hydrochloride with food and drink

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

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.



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Driving and using machines

Caution should be taken when driving or operating machines following treatment with Ketamine Hydrochloride. You should not drive or operate machines in the first 24 hours after your operation.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

3. HOW TO TAKE KETAMINE INJECTION

- Except in an emergency, Ketamine should only be used in hospitals by experienced anaesthetists with resuscitation equipment available.
- Before your operation you will usually be 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 Ketamine Hydrochloride 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, Ketamine Hydrochloride produces unconsciousness within 30 seconds and this lasts for 5 to 10 minutes. Because it works so quickly, it is important to be lying down, or supported in some other way when the drug is given. When Ketamine Hydrochloride 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 12 to 25 minutes.
- Your anaesthetist will then keep you anaesthetised with either:
 - Another anaesthetic
 - More Ketamine Hydrochloride given by injection into a muscle or vein, or in a drip (infusion)
 - Ketamine Hydrochloride together with another anaesthetic
 - When it is injected directly into a vein, Ketamine Hydrochloride is given over at least a minute so that it does not slow your breathing too much. If breathing is slowed, it can be helped 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 released from 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 are given more Ketamine Hydrochloride 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ketamine Hydrochloride can cause side effects although not



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everyone gets them.

Tell your doctor **immediately** if you notice pain, inflammation of the skin or rash at the injection site. Ketamine Hydrochloride can sometimes cause allergic symptoms ('anaphylaxis') such as breathing problems, swelling and rash. Some people have hallucinations, vivid dreams, nightmares, feel ill at ease, confused, anxious or behave irrationally while recovering from anaesthesia with Ketamine Hydrochloride. 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 3 under 'How to use Ketamine Hydrochloride').

The following side effects have been reported:

Common side effects may affect up to 1 in 10 people

The following may be experienced 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.
- 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 1000 people

- Allergic symptoms ('anaphylaxis') such as breathing problems, swelling and rash.
- Drifting in and out of consciousness (with feeling of confusion and hallucinations), flashbacks, feeling ill at ease, sleeplessness, feeling disorientated.
- Affects 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.



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Side effects where the occurrence is not known

- Raised pressure in the eyes.
- Abnormal results to liver function tests.
- Drug-induced liver injury (when taken for more than 3 days).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE KETAMINE INJECTION

- Keep this medicine out of the sight and reach of children.
- Store below 30°C
- Do not use Ketamine Injection after the expiry date which is stated on the carton and label after 'EXP'. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION.

What KETAMINE INJECTION contains

Each ml of Ketamine Injection contains 50mg of Ketamine Hydrochloride.

What KETAMINE INJECTION looks like and contents of the pack

Clear transparent liquid in 10x10ml ampoules packed in an inner carton

SUPPLIER AND MANUFACTURER

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