

Ketamine hydrochloride 10 mg/ml, 50 mg/ml and 100 mg/ml injection

What Ketamine Injection is and what it is used for

This medicine contains ketamine hydrochloride which belongs to a group of medicines called anaesthetic agents, which are used to put you to sleep during an operation. Ketamine may be used in both routine and emergency surgery. Ketamine is used in adults, the elderly and children. Ketamine can be given alone or in combination with other anaesthetic agents.

What you need to know before you are given Ketamine Injection

Do not take Ketamine:

- if you are allergic to ketamine hydrochloride
- 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 or vaginal delivery.

Warnings and precautions

Talk to your doctor or nurse if any of the following apply to you, to help them decide if Ketamine is suitable for you. If you:

- drink large amounts of alcohol
- 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

Other medicines and Ketamine

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

Ketamine is usually given together with other medicines during surgery.

When used for an operation on the chest or abdominal organs, Ketamine is usually combined with a pain-killer.

Tell your doctor if you are taking barbiturates (e.g. thiopental) and narcotics (morphinelike drugs) since use with Ketamine may slow your recovery from anaesthesia. Otherwise,

Ketamine may be used with all other general and local anaesthetics.

Ketamine with food and drink

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.

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.

Ketamine contains sodium

Ketamine 10 mg/ml Injection: Each 1 ml contains 2.6 mg of sodium. Patients on a sodium controlled diet should take this into consideration.

How Ketamine Injection is given

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 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 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 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 given by injection into a muscle or vein, or in a drip (infusion)
- Ketamine together with another anaesthetic.

When it is injected directly into a vein, Ketamine 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 than you should you may experience breathing difficulties. Your doctor or nurse may provide you with equipment to help you breath.

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

Possible side effects

Ketamine 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.

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

Common: may affect up to 1 in 10 people

- 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.
- 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.
- Page 4 of 5

Uncommon: 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.

How to store Ketamine Injection

- 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 store above 25C. Do not freeze.
- Keep the vial in the outer carton in order to protect from light