



Ketamine 50 mg/ml

solution for injection

Ketamine hydrochloride

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- If you have been given Ketamine in an emergency, you might not have had a chance to read this leaflet. Your doctor or anaesthetist would have considered the important safety information in this leaflet, but your urgent need for treatment might have been more important than some of the usual precautions.
- If you are discharged from the hospital on the same day as the operation, you should be accompanied by another adult.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Ketamine 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, elderly and children. Ketamine can be given alone or in combination with other anaesthetic agents.

2. What you need to know before you are given Ketamine

Ketamine must not be given:

- if you are allergic (hypersensitive) to ketamine hydrochloride or any of the other ingredients of this medicine (listed in section 6);
- if you are suffering from any condition in which an increase of 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 : heart failure, severe cardiovascular disease (disease of heart and blood vessels), history of stroke, brain trauma, cerebral oedema (excessive accumulation of fluid in brain), or intracerebral haemorrhage (bleeding in brain), uncontrolled hyperthyroidism and thyrotoxic crisis; or if you are suffering from severe or poorly controlled hypertension (high blood pressure);
- if you have, during your pregnancy, suffered from a condition called eclampsia or pre-eclampsia, which causes an increase in your blood pressure;
- if you are pregnant, trying to become pregnant or breast-feeding. However, Ketamine may safely be used in caesarean section surgery.

Warnings and precautions

Talk to your doctor or nurse before receiving Ketamine 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.

If, before your operation, the pressure in your spinal cord is raised, your anaesthetist will pay special attention to this during the operation.



The following information is intended for healthcare professionals only:

Ketamine is chemically incompatible with barbiturates and diazepam because of precipitate formation. Therefore, these should not be mixed in the same syringe or infusion fluid.

Diluted solution: should be used immediately.

Chemical and physical in-use stability has been demonstrated for 48 hours at 25°C protected from light. From a microbiological point of view, the product should be used immediately. If not used immediately, in use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C.

Other medicines and Ketamine

Tell your doctor if you are using, have recently used or might use 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 (morphine-like medicines) 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.

Driving and using machines

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.

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

- Do not drive while taking this medicine until you know how it affects you;
- It is an offence to drive if this medicine affects your ability to drive;
- However, you would not be committing an offence if:
 - the medicine has been prescribed to treat a medical or dental problem and
 - you have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - it was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

3. How Ketamine is given

Your doctor will explain precisely how much Ketamine you will be given, how often and for how long.

- Except in an emergency, Ketamine 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 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 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 Ketamine given to you by an 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 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 are given more Ketamine than you should

You may 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.

4. 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.

Ketamine can sometimes cause allergic symptoms ('anaphylaxis') such as breathing problems, swelling and rash.

Some people have hallucinations, vivid dreams, nightmares, feel uneasy, 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 (see Section 3 under 'How Ketamine is given').

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.

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. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ketamine

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 date 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.

6. Additional information

What Ketamine contains

- The active substance is ketamine hydrochloride. Each 10 ml solution contains 50 mg of ketamine base per ml;
- The other ingredients (excipients) are water for injections and a preservative (benzethonium chloride).

What Ketamine looks like and contents of the pack

Ketamine is a clear solution for injection or infusion available in single glass vials.

Each carton contains 5, 10 or 25 vials. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Panpharma
Z.I. du Clairay
35133 Luitré
France

Manufacturer

Panpharma GmbH
Bunsenstrasse 4
22946 Trittau
Germany

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unless dilution have taken place in controlled validated aseptic conditions.

Discard any unused product at the end of each operating session.

For single use only.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.