

Ketamine 50 mg/ml Injection
Ketamine hydrochloride

Important information about your medicine

- ▶ Your doctor or nurse will give you the injection.
- ▶ If this injection causes you any problems talk to your doctor, nurse or pharmacist.
- ▶ Please tell your doctor or pharmacist, if you have any other medical conditions or have an allergy to any of the ingredients of this medicine.
- ▶ Please tell your doctor or pharmacist, if you are taking any other medicines.

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

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

The name of your medicine is Ketamine 50 mg/ml Injection, which will be referred to as Ketamine throughout this leaflet.

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, the 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

Do not use Ketamine:

- if you are allergic 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 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 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.

Long-Term use

Ketamine is not indicated and not recommended for long-term use.

Bladder infection sometimes accompanied by bleeding, and liver problems have been reported particularly with long-term use (> 3 days) or drug abuse. See section 4 Possible side effects.

Drug Abuse and Addiction

If used on a daily basis for a few weeks, dependence and tolerance may develop, particularly in individuals with a history of drug abuse and dependence. Other adverse effects have also been reported: see "Long-Term Use".

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.

- Tell your doctor if you are taking barbiturates or narcotics (morphine-like drugs) since use with Ketamine may slow your recovery from anaesthesia. Ketamine may also decrease the effect of thiopental, a sedative medicine (barbiturate).
- Ketamine 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 Ketamine, it may:
 - cause the effect of Ketamine 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 affects the central nervous system (CNS). When Ketamine 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 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 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 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 is broken down (metabolised) in the body mainly in the liver by a particular enzyme (CYP3A4 enzyme). When Ketamine is given at the same time as other medicines which affect the activity of this enzyme, the dose of Ketamine may need to be changed to achieve the desired clinical effect.
- Diazepam can increase the effects of Ketamine so dose adjustments may be needed.
- Using sympathomimetics (for example adrenaline or noradrenaline) or vasopressin with Ketamine may lead to an increase in blood pressure and heart rate.
- Using Ketamine with ergometrine may lead to an increase in blood pressure.
- Using Ketamine with theophylline or aminophylline may lead to an increased likelihood of seizures.

The following information is intended for healthcare professionals only:

PREPARATION GUIDE:

Ketamine 50 mg/ml Injection

Please refer to the Summary of Product Characteristics for full prescribing and other information.

Therapeutic indications

Ketamine is recommended:

- As an anaesthetic agent for diagnostic and surgical procedures. When used by intravenous or intramuscular injection, Ketamine is best suited for short procedures. With additional doses, or by intravenous infusion, Ketamine 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.

Specific areas of application or types of procedures:

- When the intramuscular route of administration is preferred.

- Debridement, painful dressings, and skin grafting in burned patients, as well as other superficial surgical procedures.
- Neurodiagnostic procedures such as pneumoencephalograms, ventriculograms, myelograms, and lumbar punctures.
- Diagnostic and operative procedures of the eye, ear, nose, and mouth, including dental extractions.

Note: Eye movements may persist during ophthalmological procedures.
- Anaesthesia in poor-risk patients with depression of vital functions or where depression of vital functions must be avoided, if at all possible.
- Orthopaedic procedures such as closed reductions, manipulations, femoral pinning, amputations, and biopsies.
- Sigmoidoscopy and minor surgery of the anus and rectum, circumcision and pilonidal sinus.
- Cardiac catheterization procedures.
- Caesarean section; as an induction agent in the absence of elevated blood pressure.

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

- Ketamine is not indicated or recommended for long-term use.
- 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 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 can cause side effects although not everyone 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 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 (see Section 3 under 'How to use Ketamine').

The following side effects have been reported:

Common side effects 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.

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.
- 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 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.

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 out of the sight and reach of children.

Your doctor and pharmacist are responsible for the correct storage, use and disposal of Ketamine.

Do not use Ketamine 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.

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

6. Contents of the pack and other information

What Ketamine contains

The active substance is ketamine hydrochloride.

Each 10 ml of solution contains 577mg of ketamine hydrochloride, equivalent to 500mg of ketamine base.

The other ingredients are:

- water for injections
- benzethonium chloride (a preservative).

What Ketamine looks like and contents of the pack

Ketamine is a clear solution for injection or infusion.

Carton pack containing 1 or 10 clear glass vials of 10ml. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

hameln pharma ltd
Nexus, Gloucester Business Park,
Gloucester, GL3 4AG,
United Kingdom

Manufacturer:

Siegfried Hameln GmbH
Langes Feld 13
31789 Hameln, Germany

hameln rds s.r.o.
Horná 36
900 01 Modra
Slovak Republic

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The following information is intended for healthcare professionals only:

(Continued from overleaf)



Ketamine 50 mg/ml Injection

- Anaesthesia in the asthmatic patient, either to minimise the risks of an attack of bronchospasm developing, or in the presence of bronchospasm where anaesthesia cannot be delayed.

Administration

For intravenous infusion, intravenous injection or intramuscular injection.

Dilution

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

After dilution the solutions should be used immediately.

Incompatibilities

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.

Special precautions for storage

This medicinal product does not require any special temperature storage conditions. Do not freeze. Store in the original container.