Package leaflet: Information for the patient
KETALAR® 10 mg/ml and 50 mg/ml 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 Ketalar 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.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

2. What you need to know before you are given Ketalar Injection

❖ **Do not take Ketalar:**
- 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, Ketalar 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 Ketalar is suitable for you. 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

Ketalar 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 Ketalar

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

Ketalar is usually given together with other medicines during surgery.

- Tell your doctor if you are taking barbiturates (e.g. thiopental) and narcotics (morphine-like drugs) since use with Ketalar may slow your recovery from anaesthesia. Otherwise, Ketalar may be used with all other general and local anaesthetics.
- Diazepam can increase the effects of Ketalar so dose adjustments may be needed.
- Using sympathomimetics (for example adrenaline or noradrenaline) or vasopressin with Ketalar may lead to an increase in blood pressure and heart rate.
- Using Ketalar with ergometrine may lead to an increase in blood pressure.
- Using Ketalar with theophylline or aminophylline may lead to an increased likelihood of seizures.
- Concomitant use of medicines used to treat high blood pressure carries the risk of developing hypotension (low blood pressure).
- When given to patients already on thyroid hormone tablets, there is an increased risk of developing a fast heart rate and high blood pressure.

❖ Ketalar with food and drink

It is normal not to eat or drink for at least six hours before an operation; therefore Ketalar is usually given when your stomach is empty. If in an emergency, this is not possible, Ketalar 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 Ketalar. 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:
    o The medicine has been prescribed to treat a medical or dental problem and
    o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
    o 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.

❖ **Ketalar contains sodium**

Ketalar 10 mg/ml Injection contains 53 mg of sodium (main component of cooking/table salt) in each vial. This is equivalent to 2.65% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Ketalar Injection is given

- Ketalar is not indicated nor recommended for long-term use.
- Except in an emergency, Ketalar 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 Ketalar 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, Ketalar 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 Ketalar 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 Ketalar given by injection into a muscle or vein, or in a drip (infusion).
    - Ketalar together with another anaesthetic.
- When it is injected directly into a vein, Ketalar 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 Ketalar 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, this medicine 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.

Ketalar 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 Ketalar. 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 Ketalar Injection is given’).

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.

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.

Rare: 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.

Not known: frequency cannot be estimated from the available data

- 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 Ketalar 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.
- This medicinal product does not require any special temperature storage conditions.

- Store in the original container. Keep the vial in the outer carton in order to protect from light. Do not freeze.

6. Contents of the pack and other information

What Ketalar contains

- The active ingredient is ketamine hydrochloride

Each 20 ml solution contains 10 mg of ketamine base per ml
Each 10 ml solution contains 50 mg of ketamine base per ml

- The other ingredients are:

10 mg/ml: sodium chloride (salt) (see section 2 "Ketalar contains Sodium"), water for injections and a preservative (benzethonium chloride).
50 mg/ml: water for injections and a preservative (benzethonium chloride).

What Ketalar looks like and contents of the pack
Ketalar is a clear solution for injection or infusion available in single glass vials and comes in two strengths. Each carton contains 1 vial.

Marketing Authorisation Holder:

Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom.

Manufacturer:

Siegfried Hameln GmbH, Langes Feld 13, 31789 Hameln, Germany.

Company contact address:
For further information on this medicine please contact Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS
Telephone 01304 616161

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The following information is intended for the healthcare professional only. For full prescribing information please refer to the SmPC.

Posology and method of administration

For intravenous infusion, intravenous injection or intramuscular injection.

NOTE: All doses are given in terms of ketamine base

Ketalar is not indicated nor recommended for long-term use (see sections 4.1 and 4.4).

Adults, elderly (over 65 years) and children:
For surgery in elderly patients ketamine has been shown to be suitable either alone or supplemented with other anaesthetic agents.

Preoperative preparations

Ketalar has been safely used alone when the stomach was not empty. However, since the need for supplemental agents and muscle relaxants cannot be predicted, when preparing for elective surgery it is advisable that nothing be given by mouth for at least six hours prior to anaesthesia.

Premedication with an anticholinergic agent (e.g. atropine, hyoscine or glycopyrolate) or another drying agent should be given at an appropriate interval prior to induction to reduce ketamine-induced hypersalivation.

Midazolam, diazepam, lorazepam, or flunitrazepam used as a premedicant or as an adjunct to ketamine, have been effective in reducing the incidence of emergence reactions.

Onset and duration

As with other general anaesthetic agents, the individual response to Ketalar is somewhat varied depending on the dose, route of administration, age of patient, and concomitant use of other agents, so that dosage recommendation cannot be absolutely fixed. The dose should be titrated against the patient's requirements.

Because of rapid induction following intravenous injection, the patient should be in a supported position during administration. An intravenous dose of 2 mg/kg of bodyweight usually produces surgical anaesthesia within 30 seconds after injection and the anaesthetic effect usually lasts 5 to 10 minutes. An intramuscular dose of 10 mg/kg of bodyweight usually produces surgical anaesthesia within 3 to 4 minutes following injection and the anaesthetic effect usually lasts 12 to 25 minutes. Return to consciousness is gradual.

A. Ketalar as the sole anaesthetic agent

Intravenous Infusion

The use of Ketalar by continuous infusion enables the dose to be titrated more closely, thereby reducing the amount of drug administered compared with intermittent administration. This results in a shorter recovery time and better stability of vital signs.

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

General Anaesthesia Induction

An infusion corresponding to 0.5 – 2 mg/kg as total induction dose.

Maintenance of anaesthesia

Anaesthesia may be maintained using a microdrip infusion of 10 - 45 microgram/kg/min (approximately 1 – 3 mg/min).

The rate of infusion will depend on the patient's reaction and response to anaesthesia. The dosage required may be reduced when a long acting neuromuscular blocking agent is used.

Intermittent Injection

Induction

Intravenous Route

The initial dose of Ketalar administered intravenously may range from 1 mg/kg to 4.5 mg/kg (in terms of ketamine base). The average amount required to produce 5 to 10 minutes of surgical anaesthesia has been 2.0 mg/kg. It is recommended that intravenous administration be accomplished slowly (over a period of 60 seconds). More rapid administration may result in respiratory depression and enhanced pressor response.

Dosage in Obstetrics

In obstetrics, for vaginal delivery or in caesarean section, intravenous doses ranging from 0.2 to 1.0 mg/kg are recommended (see section 4.6 Fertility, pregnancy and lactation).

Intramuscular Route

The initial dose of Ketalar administered intramuscularly may range from 6.5 mg/kg to 13 mg/kg (in terms of ketamine base). A low initial intramuscular dose of 4 mg/kg has been used in diagnostic manoeuvres and procedures not involving intensely painful stimuli. A dose of 10 mg/kg will usually produce 12 to 25 minutes of surgical anaesthesia.

Dosage in Hepatic Insufficiency:
Dose reductions should be considered in patients with cirrhosis or other types of liver impairment (see section 4.4).

Dosage in Obstetrics

Data are lacking for intramuscular injection and maintenance infusion of ketamine in the parturient population, and recommendations cannot be made. Available data are presented in Section 5.2.

Maintenance of general anaesthesia

Lightening of anaesthesia may be indicated by nystagmus, movements in response to stimulation, and vocalization. Anaesthesia is maintained by the administration of additional doses of Ketalar by either the intravenous or intramuscular route.

Each additional dose is from ½ to the full induction dose recommended above for the route selected for maintenance, regardless of the route used for induction.

The larger the total amount of Ketalar administered, the longer will be the time to complete recovery.

Purposeless and tonic-clonic movements of extremities may occur during the course of anaesthesia. These movements do not imply a light plane and are not indicative of the need for additional doses of the anaesthetic.

B. Ketalar as induction agent prior to the use of other general anaesthetics

Induction is accomplished by a full intravenous or intramuscular dose of Ketalar as defined above. If Ketalar has been administered intravenously and the principal anaesthetic is slow-acting, a second dose of Ketalar may be required 5 to 8 minutes following the initial dose. If Ketalar has been administered intramuscularly and the principal anaesthetic is rapid-acting, administration of the principal anaesthetic may be delayed up to 15 minutes following the injection of Ketalar.

C. Ketalar as supplement to anaesthetic agents

Ketalar is clinically compatible with the commonly used general and local anaesthetic agents when an adequate respiratory exchange is maintained. The dose of Ketalar for use in conjunction with other anaesthetic agents is usually in the same range as the dosage stated above; however, the use of another anaesthetic agent may allow a reduction in the dose of Ketalar.

D. Management of patients in recovery

Following the procedure the patient should be observed but left undisturbed. This does not preclude the monitoring of vital signs. If, during the recovery, the patient shows any indication of emergence delirium, consideration may be given to the use of diazepam (5 to 10 mg I.V. in an adult). A hypnotic dose of a thiobarbiturate (50 to 100 mg I.V.) may be used to terminate severe emergence reactions. If any one of these agents is employed, the patient may experience a longer recovery period.

Incompatibilities

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

Shelf life

Ketalar 10 mg/ml and 50 mg/ml: 5 years

For single use only. Discard any unused product at the end of each operating session.

After dilution the solutions should be used immediately.

Special precautions for storage

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

Special precautions for disposal and other handling

For single use only. Discard any unused product at the end of each operating session. See section 4.2.