

**Package leaflet: Information for the patient**  
**KETALAR® 10 mg/ml, 50 mg/ml and 100 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**
- 2. What you need to know before you are given Ketalar Injection**
- 3. How Ketalar Injection is given**
- 4. Possible side effects**
- 5. How to store Ketalar Injection**
- 6. Contents of the pack and other information**

**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.

#### ❖ **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.

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

#### ❖ **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: Each 1 ml contains 2.6 mg of sodium. Patients on a sodium controlled diet should take this into consideration.

### **3. How Ketalar Injection is given**

- 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 breath.

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 or nurse. This includes any possible side effects not listed in this leaflet. You can report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). 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 date refers to the last day of that month. Your pharmacist will check this before the injection is given.
- Do not store above 25 °C. Do not freeze. Keep the vial in the outer carton in order to protect from light.

### **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

Each 10 ml solution contains 100 mg of ketamine base per ml

- The other ingredients are:

10 mg/ml: sodium chloride (salt), water for injections and a preservative (benzethonium chloride).

50 mg/ml: water for injections and a preservative (benzethonium chloride).

100 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 three strengths. Each carton contains 1 vial.

**Marketing Authorisation Holder:**

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

**Manufacturer:**

Hameln Pharmaceuticals 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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