

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being treated with KETALAR?

KETALAR contains the active ingredient ketamine hydrochloride. KETALAR belongs to a group of medicines called anaesthetics and is used to make the body insensitive to surgical treatment. It may be used in combination with other medicines to induce anaesthesia.

For more information, see Section [1. Why am I being treated with KETALAR?](#) in the full CMI.

2. What should I know before treatment with KETALAR?

Do not use if you have ever had an allergic reaction to KETALAR or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any heart conditions, recent history of stroke, brain haemorrhage or brain trauma.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before treatment with KETALAR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with KETALAR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is KETALAR given?

- KETALAR is given as an injection into a muscle or as a slow injection into a vein by a nurse or doctor.
- Your doctor will decide how much KETALAR is needed. It will depend on your condition and other factors, such as your age, weight, and other medicines that are being given.

More instructions can be found in Section [4. How is KETALAR given?](#) in the full CMI.

5. What should I know during treatment with KETALAR?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Tell any doctor or nurse giving you this medicine if you are about to be started on any new medicine; you are pregnant or planning to become pregnant; or you are breastfeeding or planning to breastfeed. |
| Things you should not do | <ul style="list-style-type: none">• When KETALAR is used on an outpatient basis, you should not be released from medical care until you have completely recovered from anaesthesia, and then you should be accompanied by a responsible adult. |
| Driving or using machines | <ul style="list-style-type: none">• KETALAR can affect driving and safe use of machinery and tools. |
| Drinking alcohol | <ul style="list-style-type: none">• Do not drink alcohol for 24 hours after you have been given KETALAR. |
| Looking after your medicine | <ul style="list-style-type: none">• KETALAR is stored in the pharmacy or on the ward.• Keep in a cool dry place, protected from light where the temperature stays below 30°C. |

For more information, see Section [5. What should I know during treatment with KETALAR?](#) in the full CMI.

6. Are there any side effects?

Common side effects are nausea and vomiting, increased saliva and pain at the injection site. Call your doctor immediately if you experience sudden signs of allergy, confusion, hallucinations, vivid imagery, nightmares, double vision or abnormal eye movements, changes in your urine, yellowing of the skin (jaundice), movements resembling seizures, breathing difficulties, rapid heart rate, or heart palpitations.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

KETALAR®

Active ingredient(s): ketamine hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using KETALAR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using KETALAR.**

Where to find information in this leaflet:

- [1. Why am I being treated with KETALAR?](#)
- [2. What should I know before treatment with KETALAR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is KETALAR given?](#)
- [5. What should I know during treatment with KETALAR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being treated with KETALAR?

KETALAR contains the active ingredient ketamine hydrochloride. KETALAR belongs to a group of medicines called anaesthetics. It works by stopping the brain from interpreting messages of pain.

KETALAR is used to make the body insensitive to surgical treatment. It may be used in combination with other medicines to induce anaesthesia.

2. What should I know before treatment with KETALAR?

Warnings

Do not use KETALAR if you:

- are allergic to ketamine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine
- have or have had any of the following medical conditions:
 - o poorly controlled blood pressure
 - o severe heart disease
 - o heart failure
 - o a recent history of stroke
 - o recent heart attack
 - o brain haemorrhage
 - o brain trauma

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have or have had any other medical conditions:
 - o heart problems, including a heart attack
 - o dehydration

- o high blood pressure
- o breathing problems, including chest infections and asthma
- o alcohol intoxication or history of alcohol abuse
- o drug abuse or drug dependence
- o cerebral or head problems, including injury, lesions or elevated cerebrospinal fluid pressure
- o psychiatric disorders (e.g. schizophrenia, acute psychosis)
- o overactive thyroid
- o glaucoma
- o kidney or liver disease (e.g. porphyria or cirrhosis)
- o seizures (e.g. fits or convulsions)

- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes

If you are not sure whether you should be given this medicine, talk to your doctor.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

Drug dependence and tolerance

Tell your doctor if you have used KETALAR or any ketamine-containing medicine before. This medicine is addictive. Individuals with a history of drug abuse or dependence may develop KETALAR dependence and tolerance. However, addiction is unlikely to occur when KETALAR is used as prescribed for anaesthesia.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with KETALAR and affect how it works. These include:

- general anaesthetics (medicines used to put you to sleep during an operation) and hypnotics (e.g. thiopental)
- barbiturates (used to treat epilepsy)
- narcotic analgesics (used to relieve pain)
- sedatives or anxiolytic drugs (used to help relieve anxiety)

- alcohol
- benzodiazepines (medicines used as sedatives or to treat anxiety)
- ergometrine (a medicine used sometimes after giving birth)
- thyroxine or thyroid hormones
- theophylline and aminophylline (medicines used for breathing problems or asthma)
- antihypertensives (medicines used to help lower blood pressure)
- muscle relaxants used in anaesthesia (atracurium and tubocurarine)
- antidiuretic hormones (e.g. vasopressin)
- medicines affecting your heart or circulation system (medicines that increase your blood pressure should be avoided)

These medicines may be affected by KETALAR or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect KETALAR.

4. How is KETALAR given?

How much will be given

- Your doctor will decide what dose you will receive.
- This depends on your condition and other factors, such as your age, weight and other medicines that are being given.

How is KETALAR given

- KETALAR is given as an injection into a muscle, or as a slow injection into a vein. It must only be given by a nurse or doctor.

If too much KETALAR is given

As KETALAR is given to you in a hospital under the supervision of your doctor, it is unlikely that you will receive an overdose. You will be closely monitored in hospital during the early post-operative period so that any unwanted side effects can be treated. However, if you experience severe side effects, tell your doctor immediately.

Symptoms of an overdose may include the side effects listed under Section [6. Are there any side effects?](#) If you think that you have been given too much KETALAR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know during treatment with KETALAR?

Things you should do

Tell any doctor or nurse giving you this medicine if you:

- are about to be started on any new medicine
- are pregnant or planning to become pregnant
- are breastfeeding or are planning to breastfeed

Remind any doctor, dentist or pharmacist you see that you are being given KETALAR.

Keep all of your doctor's appointments so that your progress can be checked.

Things you should not do

When KETALAR is used on an outpatient basis, you should not be released from medical care until you have completely recovered from anaesthesia, and then you should be accompanied by a responsible adult.

Driving or using machines

Be careful before you drive or use any machines or tools for at least 24 hours after receiving KETALAR until you know how the medicine affects you.

KETALAR has the potential to affect driving and has an associated risk with road safety.

Drinking alcohol

Do not drink alcohol for 24 hours after you have been given this medicine.

Tell your doctor if you drink alcohol.

How is KETALAR stored

- KETALAR will be stored in the pharmacy or on the ward.
- Store below 30°C. Keep the medicine in a cool dry place, protected from light.

Keep it where young children cannot reach it.

When to discard KETALAR

KETALAR is used for one dose in one patient only. Any remaining contents should be discarded.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

| Common side effects | What to do |
|--|---|
| <ul style="list-style-type: none">Nausea or vomitingIncreased salivaPain at the injection site | <p>Speak to your doctor if you have any of these side effects and they worry you.</p> <p>Do not be alarmed by this list of side effects. You may not experience any of them.</p> |

Serious side effects

| Serious side effects | What to do |
|--|--|
| <p>Allergic type reactions</p> <ul style="list-style-type: none">Sudden signs of allergy such as rash or hives, swelling of the face, lips or tongue, wheezing or difficulty breathing <p>Psychological</p> <ul style="list-style-type: none">Confusion, excitation, irrational behaviourHallucinations, vivid imagery, dream-like states, nightmaresAgitation, anxiety or insomnia <p>Nervous system</p> <ul style="list-style-type: none">Movements resembling seizures <p>Lung related issues</p> <ul style="list-style-type: none">Breathing difficulties <p>Heart related issues</p> <ul style="list-style-type: none">Elevated blood pressure, fast or slow heartbeat, heart palpitations, feeling faint <p>Eye related issues</p> <ul style="list-style-type: none">Double vision or abnormal eye movements <p>Kidney related issues</p> <ul style="list-style-type: none">Changes in your urine colour, pain or burning sensation when urinating, frequently passing small amounts of urine or a persistent urge to urinate <p>Liver related issues</p> <ul style="list-style-type: none">Yellowing of the skin (jaundice) | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What KETALAR contains

| | |
|---|---|
| Active ingredient (main ingredient) | 200 mg/2 mL of ketamine as hydrochloride |
| Other ingredients (inactive ingredients) | Benzethonium chloride Water for injections |

Do not use this medicine if you are allergic to any of these ingredients.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What KETALAR looks like

KETALAR is a clear, colourless solution in a glass vial.

KETALAR 200 mg/2 mL, 5 x 2 mL vials.

Australian Registration Number: AUST R 70073.

Who distributes KETALAR

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

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