KETALAR®

ketamine hydrochloride (key-tar-mean)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about KETALAR®. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Ketamine Injection against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.
You may need to read it again.

What KETALAR® is used for

KETALAR® is used to make the body insensitive to surgical treatment. It may be used in combination with other medicines to induce anaesthesia (an-es-these-ee-ya).

This medicine belongs to a group of medicines called anaesthetics (an-es-thet-icks).

It works by stopping the brain from interpreting messages of pain.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.
Your doctor may have prescribed it for another reason.

This medicine is addictive.

Individuals with a history of drug abuse of dependence may develop KETALAR® dependence and tolerance, however, addiction is unlikely to occur when ketamine as hydrochloride is used as prescribed for anaesthesia.

It is available only with a doctor's prescription.

Before you are given KETALAR® Injection

When you must not be given it

You must not be given KETALAR® Injection if you have an allergy to:

- any medicine containing ketamine
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

You must not be given this medicine if you have or have had any of the following medical conditions:

- poorly controlled blood pressure
- severe heart disease
- heart failure
- a recent history of stroke
- recent heart attack
- brain haemorrhage
- brain trauma

You must not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

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

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.
Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given KETALAR®.

Taking other medicines

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

Some medicines and KETALAR® may interfere with each other. These include:

- general anaesthetics (medicines used to put you to sleep during an operation) and hypnotics (eg. thiopental)
- barbiturates (used to treat epilepsy or narcotic analgesics (used to relieve pain)
- sedatives or anxiolytic drugs (medicine 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, a medicine used for breathing problems or asthma
- antihypertensives (medicine used to help lower high blood pressure)
- muscle relaxants used in anaesthesia (atracurium and tubocurarine)
- Antidiuretic hormones, such as vasopressin
- Medicines affecting your heart or circulation system (medicines that increase your blood pressure should be avoided)

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being treated with this medicine.

If you are not sure whether you should be given ketamine, talk to your doctor or pharmacist.

How KETALAR® is given

How much is given

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

How it is 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 you receive too much (overdose)

As KETALAR® is given to you in a hospital under the supervision of your doctor, it is very 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 below in the 'Side Effects' section but are usually of a more severe nature.

Ask your doctor or pharmacist if you have any concerns.

In case of overdose, immediately contact the Poisons Information Centre 13 11 26 or go to Accident and Emergency at the nearest hospital. Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

While you are being given KETALAR®

Things you must do

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

Things to be careful of

Be careful driving or operating machinery or engage in hazardous activities for at least 24 hours after receiving KETALAR®.

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

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

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with KETALAR®.

KETALAR® may have unwanted side effects in a few people. All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.
You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- nausea, vomiting
- increased saliva
- pain at the injection site

The above list includes the more common side effects of your medicine.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- rash
- double vision or abnormal eye movements

The above list includes serious side effects which may require medical attention.

If any of the following happen, tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as rash or hives, swelling of the face, lips or tongue, wheezing or difficulty breathing
- confusion, excitation, irrational behaviour
- hallucinations, vivid imagery, dream-like states, nightmares
- movements resembling seizures
- breathing difficulties
- elevated blood pressure, rapid pulse rate, heart palpitations

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using KETALAR®

Storage

KETALAR® will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light where the temperature stays below 30°C

Disposal

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

Product description

What it looks like

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

Ingredients

KETALAR® contains 200 mg/2 mL of ketamine as hydrochloride as the active ingredient.

It also contains:

- benzethonium chloride (phemerol)
- water for injections

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

Supplier / Sponsor

KETALAR® is supplied by:

Australian Sponsor:

Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3
500 Collins Street
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Pfizer New Zealand Limited
PO Box 3998
Auckland, New Zealand
Toll Free Number: 0800 736 363

KETALAR® 200 mg/2 mL,5 X 2 mL vials AUST R 70073

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