

Ketamine APOTEX

Solution for Injection

Contains the active ingredient ketamine hydrochloride

Consumer Medicine Information

For a copy of a large print leaflet,
Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully for information about your medicine.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

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

What this medicine is used for

The name of your medicine is Ketamine Apotex solution for injection. It contains the active ingredient ketamine hydrochloride.

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

This medicine belongs to a group of medicines called anaesthetics.

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 this medicine for another reason.

This medicine is addictive.

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

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

Before you are given this medicine

When you must not be given this medicine

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 are hypersensitive to, or have had an allergic reaction to ketamine.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, discuss this with your doctor or nurse immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

Before you are given it

Before you are given this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - heart problems, including 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 (e.g. schizophrenia, acute psychosis)
 - overactive thyroid
 - glaucoma
 - kidney or liver disease (e.g. porphyria or cirrhosis)
 - seizures fits or convulsions.
3. You are currently pregnant or you plan to become pregnant, or are breastfeeding.
4. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with ketamine. 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 (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, 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).

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with ketamine.

How this medicine 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

Ketamine 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 ketamine 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 'Possible side effects' section but are usually of a more severe nature.

In the case an overdose, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your 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 this medicine

Things you must do

Tell any doctor or nurse that have been given this medicine if:

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

Keep all 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 ketamine.

When ketamine 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.

Possible side effects

Tell your doctor or nurse as soon as possible if you do not feel well when you are given ketamine or if you have any questions or concerns.

Ketamine may have unwanted side effects in a few people.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

- 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.

These may be serious side effects and you may need medical attention:

- rash
- double vision or abnormal eye movements.

If you experience any of the following tell your doctor or nurse immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- confusion, excitation, irrational behaviour
- hallucinations, vivid imagery, dream-like states, nightmares
- movements resembling seizures
- breathing difficulties
- elevated blood pressure, rapid pulse rate, heart palpitations.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to ketamine tell your doctor or nurse immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Ketamine 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

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

Product description

What Ketamine APOTEX Solution for Injection looks like

A clear and colourless to slightly yellow solution, essentially free from visible particulate matter.

Ingredients

Each ampoule contains 200mg of ketamine (as hydrochloride) as the active ingredient.

It also contains the following inactive ingredient:

- Water for injections

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

Ketamine APOTEX 200mg/2mL solution for injection, 2mL ampoule pack (type I clear glass).

Available in packages of 5 ampoules: AUST R 219040.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

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