

Ketamine APOTEX
Solution for Injection
Ketamine hydrochloride

Consumer Medicine Information

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

What is in this leaflet

This leaflet answers some common questions about this medicine. 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 using this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with you.

You may need 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.

Ketamine 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 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 an allergy to:

- ketamine
- any of the ingredients listed at the end of the leaflet

Some of the 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

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 be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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 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)

Tell your doctor if you are currently pregnant, plan to become pregnant, or are breastfeeding.

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

If you have not told your doctor about any of the above, tell them before you are given this medicine.

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 ketamine may interfere with each other. These include:

- general anaesthetics (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 (used as sedatives or to treat anxiety)
- ergometrine (used sometimes after giving birth)
- thyroxine or thyroid hormones
- theophylline (used for breathing problems or asthma)
- antihypertensives (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, or that increase your blood pressure

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 taking this medicine.

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, weight 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 'Side Effects' section but are usually of a more severe nature.

In the case of an overdose, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) 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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are being given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given this medicine.

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

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

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things to be careful of

Be careful driving, operating machinery or engaging 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 then you should 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 when you are given ketamine.

Ketamine 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:

- 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

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

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

- signs of an allergic reaction, such as 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
- confusion, excitation, irrational behaviour
- hallucinations, vivid imagery, dream-like states, nightmares
- movements resembling seizures
- breathing difficulties
- elevated blood pressure, rapid pulse rate, heart palpitations

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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

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

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

200mg/2mL solution for injection, 2mL ampoule (type I clear glass):

A clear and colourless to slightly yellow solution, essentially free from visible particulate matter. AUST R 219040.

Available in packages of 5 ampoules.

Ingredients

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

It also contains the following:

- water for injections

This medicine does not contain any gluten, lactose, sucrose, tartrazine and is free of other azo dyes.

Sponsor

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This leaflet was last updated in September 2019.