

Flumazenil APOTEX Solution for Injection

Contains the active ingredient flumazenil

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 flumazenil. 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 or pharmacist:

- 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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

What this medicine is used for

The name of your medicine is Flumazenil APOTEX solution for injection. It contains the active ingredient flumazenil.

It is used to reverse benzodiazepine overdose, both suspected and known.

It is given to arouse people after surgery or benzodiazepine overdose.

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.

There is no evidence that this medicine is addictive.

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

Before you are given this medicine

When you must not be given it

Do not use this medicine if:

- **You are taking a benzodiazepine for control of a potentially life-threatening condition**
- **You are hypersensitive to, or have had an allergic reaction to, flumazenil or any of the ingredients listed at the end of this leaflet.**

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, do not take any more of the medicine and contact your doctor 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

Your doctor must know about all the following before you are given this medicine.

You must 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:
 - you suffer from epilepsy
 - you have severe liver disease
 - you suffer from panic disorder
 - you have been taking high doses of benzodiazepines and/or you

have been taking benzodiazepines for a long time.

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:

- benzodiazepines e.g. diazepam, bromazepam, temazepam etc.
- sedating agents, e.g. zopiclone
- anticonvulsants
- antidepressants

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 flumazenil.

How this medicine is given

How much of this medicine 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.

Usually only a single dose of this medicine is required.

How it is given

This medicine is given as an injection into a vein. This medicine must only be given by an anaesthetist or experienced physician.

If you receive too much (overdose)

As flumazenil 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 while in the hospital 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.

While you are using this medicine

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

This medicine may cause drowsiness or dizziness in some people. This can be due to the possibility of re-sedation within the first 24 hours after administration.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness in the first 24 hours after administration which may increase the risk of a fall.

There is also a possibility of other benzodiazepine effects such as difficulty in breathing, within the first 24 hours after administration.

Possible side effects

Tell your doctor as soon as possible if you do not feel well after you have been given flumazenil or if you have any questions or concerns.

This medicine helps most people who experience an overdose with benzodiazepine medicines but it 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 if you notice any of the following:

- nausea with or without vomiting
- dizziness, lightheadedness
- feeling anxious or fearful
- rapid or irregular heart beat
- depression, tearfulness with or without agitation

These may be related to the reversal of anaesthetic.

Allergic reactions

If you think you are having an allergic reaction to flumazenil, do not take any more of this medicine and tell your doctor 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.

After using this medicine

Storage

This medicine will be stored in the pharmacy or on the ward. It is kept in a cool dry place where the temperature stays below 30°C.

Disposal

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

Product description

What Flumazenil APOTEX solution for injection looks like

A clear and colourless sterile solution, free from visible particles.

Ingredients

Each ampoule contains 0.5 mg/5mL of flumazenil as the active ingredient.

It also contains the following inactive ingredients:

- disodium edetate
- glacial acetic acid
- sodium chloride
- sodium hydroxide
- water for injections

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

Australian Registration Numbers

Flumazenil APOTEX 0.5 mg/5mL solution for injection ampoule (Type I clear glass): AUST R 236672.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

APO and APOTEX are registered trade marks of Apotex Inc.

This leaflet was last updated in February 2016.