

Flumazenil Kabi

Flumazenil Kabi Solution for Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Flumazenil Kabi injection. 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 Flumazenil Kabi 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 Flumazenil Kabi is used for

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

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

Your doctor may have prescribed Flumazenil Kabi for another reason.

Ask your doctor if you have any questions why Flumazenil Kabi has been prescribed for you.

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

Before you are given Flumazenil Kabi

When you must not be given it

Flumazenil Kabi must not be given if you have any allergies to

- Any medicine containing flumazenil or
- Any of the ingredients listed at the end of this leaflet

You must not be given this medicine if you are taking a benzodiazepine for control of a potentially life-threatening condition.

Before you are given it

Your doctor must know about all the following before you are given Flumazenil Kabi.

You must tell your doctor if:

- **You are allergic to any other medicines or any other substances such as foods, preservatives or dyes**
- **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.**

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

Taking other medicines

You must tell your doctor if you are taking any other medicines, including any that you have bought from a pharmacy, supermarket or health food shop.

Some medicines may interfere with Flumazenil Kabi or affect how well it works. These medicines include:

- benzodiazepines e.g. diazepam (Valium[®]), bromazepam (Lexotan[®]), temazepam (Temaze[®], Normison[®]) etc.
- anticonvulsants
- antidepressants

How Flumazenil Kabi is given

Flumazenil Kabi is given as an injection into the vein. Flumazenil Kabi must only be given by an anaesthetist or experienced physician.

Your doctor will decide what dose of Flumazenil Kabi you will receive. This depends on your condition.

Usually only a single dose of Flumazenil Kabi is required.

While you are using Flumazenil Kabi

Things to be careful of

Be careful driving or operating machinery until you know how Flumazenil Kabi 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 of Flumazenil Kabi.

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

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.

Side Effects

Tell your doctor, pharmacist or nurse as soon as possible if you do not feel well after you have been given Flumazenil Kabi.

Flumazenil Kabi helps most people who experience an overdose with benzodiazepine medicines but it may have unwanted side effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

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

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

- depression, tearfulness with or without agitation
- allergic reactions, including sudden life threatening reactions. Symptoms 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.

These may be related to the reversal of anaesthetic.

After using Flumazenil Kabi

Storage

Flumazenil Kabi will be stored in the pharmacy or on the ward. It is kept in a cool dry place where the temperature stays below 25°C.

Product Description

What it looks like

Flumazenil Kabi is a clear colourless solution in glass ampoules.

Flumazenil Kabi comes in 5 mL and 10 mL ampoules in packs of 5 and 10.

Ingredients

Flumazenil Kabi contains the active ingredient flumazenil. Each ampoule contains 0.1 mg/mL flumazenil as the active ingredient.

It also contains:

- Disodium edetate
- Glacial acetic acid (260)
- Sodium chloride
- Sodium hydroxide
- Water for injections

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

5 mL ampoule: AUST R 260016 contains 0.5 mg flumazenil

10 mL ampoule: AUST R 260017 contains 1mg flumazenil

Sponsor

Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way
Mount Kuring-gai NSW 2080
Australia
Telephone: (02) 9391 5555

Fresenius Kabi New Zealand Limited
60 Pavilion Drive
Airport Oaks, Auckland 2022
New Zealand
Freecall: 0800 144 892

® = Registered Trademark

This leaflet was prepared in April, 2019