

Flumazenil-Clarix

Flumazenil 0.5 mg/5 mL and 1 mg/10 mL, solution for injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Flumazenil-Clarix. 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-Clarix 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-Clarix is used for

Flumazenil-Clarix 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-Clarix for another reason. **Ask your doctor if you have any questions why Flumazenil-Clarix has been prescribed for you.**

Before you are given Flumazenil-Clarix

When you must not be given it

Do not use Flumazenil-Clarix if:

- you have had an allergic reaction to Flumazenil-Clarix or any of the ingredients listed at the end of this leaflet
- 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-Clarix.

You must tell your doctor if:

1. you are allergic to any other medicines or any other substances such as foods, preservatives or dyes
2. you suffer from epilepsy
3. you have severe liver disease
4. you suffer from panic disorder
5. 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 them before you are given Flumazenil-Clarix.

Taking other medicines

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-Clarix or affect how well it works. These medicines include:

- benzodiazepines e.g. diazepam (Valium), bromazepam

(Lexotan), temazepam (Temaze, Normison) etc.

- anticonvulsants
- antidepressants

How Flumazenil-Clarix is given

Flumazenil-Clarix is given as an injection into a vein. Flumazenil-Clarix must only be given by an anaesthetist or experienced physician.

Your doctor will decide what dose of Flumazenil-Clarix you will receive. This depends on your condition. Usually only a single dose of Flumazenil-Clarix is required.

While you are using Flumazenil-Clarix

Things to be careful of

Be careful driving or operating machinery until you know how Flumazenil-Clarix 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-Clarix.

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.

Side Effects

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

Flumazenil helps most people who experience an overdose with benzodiazepine medicines but it 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 treatment if you get some of the side effects.

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

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

- nausea with or without vomiting
- dizziness, light-headedness
- feeling anxious or fearful
- rapid or irregular heart beat
- depression, tearfulness with or without agitation
- allergic reactions, including sudden life threatening allergic 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 being given Flumazenil-Claris

Flumazenil-Claris 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.

Product Description

What it looks like

Flumazenil-Claris is available as a clear, solution at a concentration of 0.1mg per mL in 5 mL and 10 mL glass ampoules. It comes in packs of 5 and 10 ampoules.

Ingredients

Each 5 mL Flumazenil-Claris ampoule contains 0.5 mg flumazenil as the active ingredient.

Each 10 mL Flumazenil-Claris ampoule contains 1 mg flumazenil as the active ingredient.

Flumazenil-Claris also contains:

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

Each mL of Flumazenil-Claris contains approximately 3.5 mg sodium. This medicine does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Distributor

AFT Pharmaceuticals Pty Ltd
296 Burns Bay Road
Lane Cove
Sydney 2066

Flumazenil-Claris 0.5 mg/5 mL:
AUST R 231405

Flumazenil-Claris 1 mg/10 mL:
AUST R 231406

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