

DBL™ Flumazenil Injection

Flumazenil (flew-MAZ-ah-nill)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Flumazenil Injection (flumazenil). 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 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 DBL™ Flumazenil Injection is used for

DBL™ Flumazenil Injection is used to reverse benzodiazepine overdose, both suspected and known.

It is given to arouse people after surgery involving benzodiazepine when required.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

It is available only with a doctor's prescription.

Before you are given DBL™ Flumazenil Injection

When you must not be given it

You must not be given DBL™ Flumazenil Injection if you have an allergy to:

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

Some of the symptoms of an allergic reaction may 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.

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 DBL™ Flumazenil Injection.

You must tell your doctor if:

- you are allergic to 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 taken 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.

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 flumazenil may interfere with each other. These include:

- benzodiazepines eg diazepam, bromazepam, temazepam etc
- anticonvulsants
- antidepressant

How DBL™ Flumazenil Injection 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 weight.

How it is given

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

Usually only a single dose of DBL™ Flumazenil Injection is required.

If you receive too much (overdose)

As DBL™ Flumazenil Injection is given to you in a hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose. 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.

Ask your doctor or pharmacist if you have any concerns.

In case of overdose, immediately contact the Poisons Information Centre for advice on management (in Australia call 13 11 26; in New Zealand call 0800 764 766).

While you are being given DBL™ Flumazenil Injection

Things to be careful of

Do not drive or operate machinery until you know how DBL™ Flumazenil Injection affects you.

DBL™ Flumazenil Injection may cause drowsiness or dizziness in some people and therefore may affect alertness. This is due to the possibility of resedation within the first twenty four hours after administration. Make sure you know how you react to DBL™ Flumazenil Injection before you drive a car or 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 or nurse as soon as possible if you do not feel well after being treated with DBL™ Flumazenil Injection.

This medicine 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 these side effects.

Ask your doctor to answer any questions you may have.

Tell your doctor, nurse or pharmacist 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 heartbeat
- depression, tearfulness with or without agitation

These may be related to the reversal of anaesthetic.

After using DBL™ Flumazenil Injection

Storage

DBL™ Flumazenil Injection will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, where the temperature stays below 25°C.

Product description

What it looks like

DBL™ Flumazenil Injection is a clear solution in a glass ampoule.

Ingredients

DBL™ Flumazenil Injection ampoules contain 0.1mg/mL of Flumazenil in aqueous solution as the active ingredient. It also contains:

- disodium edetate
- acetic acid
- sodium chloride
- sodium hydroxide in water for injections adjusted to pH 4.0.

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

Sponsor

Australian Sponsor:

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New Zealand Sponsor:

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AUST R Number(s):

- 0.5mg/mL x 5 ampoules
AUST R 121098

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