

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

FLUMAZENIL 0,5 mg/5 mL FRESENIUS

FLUMAZENIL 1,0 mg/10 mL FRESENIUS

Solution for injection/infusion

Flumazenil

Sugar free

Read all of this leaflet carefully before you are given FLUMAZENIL FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- FLUMAZENIL FRESENIUS has been prescribed for you personally.

What is in this leaflet

1. What FLUMAZENIL FRESENIUS is and what it is used for
2. What you need to know before you are given FLUMAZENIL FRESENIUS
3. How FLUMAZENIL FRESENIUS will be administered
4. Possible side effects
5. How to store FLUMAZENIL FRESENIUS
6. Contents of the pack and other information.

1. What FLUMAZENIL FRESENIUS is and what it is used for

FLUMAZENIL FRESENIUS is an antidote for the central sedative effects of benzodiazepines (medicines with sedative, sleep inducing, muscle relaxing and anxiolytic properties).

FLUMAZENIL FRESENIUS may be used in anaesthesia to wake you up after certain diagnostic tests or in intensive care if you have been held under sedative conditions.

FLUMAZENIL FRESENIUS may also be used for the diagnosis and treatment of intoxications or overdose with benzodiazepines.

2. What you need to know before you are given FLUMAZENIL FRESENIUS

FLUMAZENIL FRESENIUS should not be administered to you:

- If you are hypersensitive (allergic) to flumazenil or any of the other ingredients of FLUMAZENIL FRESENIUS (listed in section 6).
- If benzodiazepines have been administered to you to control a potentially life-threatening situation (for example control of pressure in the brain or a serious epileptic seizure).

Warnings and precautions

Special care should be taken with FLUMAZENIL FRESENIUS:

- If you have epilepsy and have taken benzodiazepines for a long period. FLUMAZENIL FRESENIUS is not recommended as flumazenil can cause seizures.
- If your liver is not working well, flumazenil elimination can be delayed.
- If you have or in the past have had a serious head injury. FLUMAZENIL FRESENIUS can cause an increased pressure in your brain.
- If you were anxious before an operation or had an anxious seizure or have long-term anxiety.
- If you had panic attacks in the past. FLUMAZENIL FRESENIUS can cause new attacks.
- If you had long-term (chronic) or high dose treatment with benzodiazepines. Rapid injection of high doses of FLUMAZENIL FRESENIUS (more than 1 mg) can cause withdrawal symptoms.
- If you have a history of alcohol or other substance abuse, as you have a higher risk of benzodiazepine tolerance and dependence. Your anaesthetist will adjust your dose carefully.

Beware also of the following:

FLUMAZENIL FRESENIUS only reverses the effects of benzodiazepines.

- If lowering of consciousness or sedation is caused by another medicine, it is unlikely that FLUMAZENIL FRESENIUS will counteract it.
- As the action of flumazenil, as in FLUMAZENIL FRESENIUS, is usually shorter than that of benzodiazepines, re-sedation may possibly recur. You will be closely observed, possibly in the intensive care unit until the effects of flumazenil have gone away.
- If you undergo an operation that is particularly invasive and causes a lot of pain, the anaesthetist may keep you in a sedated condition.
- FLUMAZENIL FRESENIUS is not recommended for the treatment of benzodiazepine dependence or for the treatment of benzodiazepines-withdrawal-symptoms.
- If FLUMAZENIL FRESENIUS is administered to you at the end of your operation to wake you up, it should not be given until the effects of muscle relaxants have gone away.
- If you do not wake up after FLUMAZENIL FRESENIUS is administered, another reason for this will be considered because FLUMAZENIL FRESENIUS specifically reverses the effects of benzodiazepines.
- Seizures or other toxic effects can be more severe in cases of mixed medicine overdose (e.g. intoxication with benzodiazepines and cyclic antidepressants).
- If you have been treated for long periods with high doses of benzodiazepines, the advantages of the use of FLUMAZENIL FRESENIUS should be carefully weighed against the risk of withdrawal symptoms.

Other medicines and FLUMAZENIL FRESENIUS

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you take:

- medicines working in the same way as benzodiazepines e.g. zopiclone and triazolopyridazine (used to treat insomnia). FLUMAZENIL FRESENIUS may decrease the effects of these medicines;
- benzodiazepines (e.g. diazepam, midazolam, flunitrazepam);
- tricyclic or tetracyclic antidepressants or other treatments for mental illness (such as amitriptyline, imipramine, mirtazapine, mianserin).

When using FLUMAZENIL FRESENIUS in cases of an accidental overdose it will be considered that the toxic effects of other psychotropic medicines (especially tricyclic antidepressants like imipramine) taken concurrently, may increase with the subsidence of the benzodiazepine effect.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving this medicine.

Safety of FLUMAZENIL FRESENIUS during pregnancy has not been established. You should therefore not use FLUMAZENIL FRESENIUS if you are pregnant or planning to become pregnant.

It is not known whether FLUMAZENIL FRESENIUS is excreted in breastmilk. You should therefore not breastfeed your baby for 24 hours after FLUMAZENIL FRESENIUS has been given.

Driving and using machines

After you have received FLUMAZENIL FRESENIUS the effects of benzodiazepines can come back. You must not drive a car, operate machinery or do strenuous activity for at least 24 hours after FLUMAZENIL FRESENIUS treatment. Ensure that you do not take part in these activities until you are aware of the measure to which FLUMAZENIL FRESENIUS affects you.

FLUMAZENIL FRESENIUS contains sodium chloride

FLUMAZENIL FRESENIUS contains 3,7 mg sodium per mL (18,5 mg/5 mL ampoule size or 37 mg/10 mL ampoule size) solution for injection. This is to be taken into consideration if you are on a controlled sodium diet.

3. How FLUMAZENIL FRESENIUS will be administered

You will not be expected to give yourself FLUMAZENIL FRESENIUS. It will be given to you by a person who is qualified to do so.

FLUMAZENIL FRESENIUS is administered as intravenous injection (into a vein) or diluted as intravenous infusion (over a longer period).

For single use only, any unused contents must be discarded.

The usual dose is an initial dose of 200 micrograms administered into your vein over 15 seconds.

Your doctor will decide on the dose and will tell you how long your treatment with FLUMAZENIL FRESENIUS will last.

Do not stop treatment early. If you have the impression that the effect of FLUMAZENIL FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

If you receive more FLUMAZENIL FRESENIUS than you should

Since a healthcare provider will administer FLUMAZENIL FRESENIUS, he/she will control the dosage. However, in the event of overdose your doctor will manage the overdose.

If you forget to use FLUMAZENIL FRESENIUS

Since a healthcare provider will administer FLUMAZENIL FRESENIUS, it is unlikely that the dose will be missed.

If you stop using FLUMAZENIL FRESENIUS

If your treatment is stopped too soon, your symptoms will resume. Your doctor will decide when you have recovered enough to stop treatment.

4. Possible side effects

FLUMAZENIL FRESENIUS can have side effects.

Not all side effects reported for FLUMAZENIL FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FLUMAZENIL FRESENIUS, please consult your healthcare provider for advice.

If any of the following happens, tell your doctor immediately:

- sudden wheezing, difficulty in breathing, swelling of the eyelids, mouth, face, lips or throat;
- rash or itching (especially affecting your whole body).

These are all very serious side effects. If you have them, you may have had a serious reaction to FLUMAZENIL FRESENIUS. You may need urgent medical attention or further hospitalisation.

Tell your doctor immediately if you notice any of the following:

- palpitations (irregular heartbeats), tachycardia or bradycardia (fast or slow heart rate), extrasystoles (premature contractions of the heart), chest pain;
- seizures - in patients suffering from epilepsy or severe liver disease, mainly after long-term treatment with benzodiazepines or other medicines that may be abused.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- anxiety
- strong emotional lability
- having problems in initiating and maintaining sleep (insomnia)
- feeling sleepy (somnolence)
- dizziness (vertigo)
- headache

- agitation
- involuntary trembling or quivering (tremor)
- dry mouth
- hyperventilation (breathing very quickly)
- speech disorder
- skin sensations (e.g. cold, warmth, tingling, pressure, etc.) in the absence of stimulation (paraesthesia)
- double vision
- strabismus (a condition in which the eyes are not properly aligned with each other)
- increase in lacrimation (teary eyes)
- hypotension (low blood pressure), orthostatic hypotension (low blood pressure on transition from lying to standing)
- transient increased blood pressure
- nausea (feeling sick) (after operation), vomiting (after operation, particularly if opiates have been used), hiccups.
- sweating, flushing
- pain at the injection site

Frequently after rapid injection (not requiring treatment):

- anxiety
- agitation
- heart palpitations

Less frequent side effects

- fear
- hearing affected, hearing abnormally well, ringing in the ears
- slow or rapid heart action

- premature beat of your heart (extrasystole)
- hypertension (too high blood pressure)
- difficulty in breathing
- cough
- nasal congestion
- chest pain
- chills, shivering

Frequency not known

- withdrawal symptoms (agitation, anxiety, emotional lability, confusion, drowsiness, insomnia, sense-related distortion),
- panic attacks, abnormal crying, agitation, aggressive reactions
- fatigue, injection site pain, reddening of the skin, rash at injection site
- inflammation of a vein caused by a blood clot (thrombophlebitis).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of FLUMAZENIL FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store FLUMAZENIL FRESENIUS

Store all medicines out of reach of children.

Store at or below 25 °C.

This medicine is for single use only and should be used immediately after opening. Chemical and physical in-use stability has been demonstrated for 24 hours at 25 °C. From a microbiological point of view, unless the method of dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Do not store in a bathroom.

Do not use after the expiry date stated on the label and carton.

Do not use this medicine if the solution is not clear and free from particles.

Any unused solution should be discarded in accordance with local requirements.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). Return all unused medicines to your pharmacist.

6. Contents of the pack and other information

What FLUMAZENIL FRESENIUS contains

- The active substance is flumazenil

Each millilitre contains 0,1 mg flumazenil. Each ampoule with 5 mL solution contains 0,5 mg flumazenil. Each ampoule with 10 mL solution contains 1,0 mg flumazenil.

- The other ingredients are disodium edetate, glacial acetic acid, sodium chloride, sodium hydroxide solution (for pH-adjustment), water for injections.

What FLUMAZENIL FRESENIUS looks like and contents of the pack

FLUMAZENIL FRESENIUS is a clear and colourless solution, free from visible particles.

FLUMAZENIL 0,5 mg/5 mL FRESENIUS:

Carton boxes with 5 or 10 clear colourless glass ampoules containing 5 mL solution.

FLUMAZENIL 1,0 mg/10 mL FRESENIUS:

Carton boxes with 5 or 10 clear colourless glass ampoules containing 10 mL solution.

Not all packaging sizes may be marketed.

Holder of Certificate of Registration

FRESENIUS KABI SOUTH AFRICA (PTY) LTD

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Registration numbers

Flumazenil 0,5 mg/5 ml Fresenius: 46/34/0063

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Access to the corresponding Professional Information

The professional information will be printed and packed with the product.