PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

FLUMAZENIL 5 ML B. BRAUN (0,5 mg/5 ml), solution for injection

FLUMAZENIL 10 ML B. BRAUN (1 mg/10 ml), solution for injection

Flumazenil

Read all of this leaflet carefully before you are given FLUMAZENIL B. BRAUN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What FLUMAZENIL B. BRAUN is and what it is used for

FLUMAZENIL B. BRAUN is a counteragent (antidote) for a specific group of medicines called benzodiazepines. Benzodiazepines have sedative, sleep inducing and muscle relaxing properties. They are used to make you sleepy and tranquillize you if you are anxious. FLUMAZENIL B. BRAUN may completely or partially reverse these effects.

Adult patients

FLUMAZENIL B. BRAUN may therefore be used:

- in anesthesia to wake you up after surgery or certain diagnostic tests.
- for the diagnosis and treatment of intoxications or overdose with benzodiazepines.

2: What you need to know before you use FLUMAZENIL B. BRAUN

Do not use FLUMAZENIL B. BRAUN

- if you are allergic to FLUMAZENIL B. BRAUN or any of the other ingredients of FLUMAZENIL B. BRAUN (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 B. BRAUN

- if you are epileptic and have received benzodiazepine treatment for a long period of time. In this case the administration of FLUMAZENIL B. BRAUN can cause seizures
- if you have a serious brain injury (and/or instable pressure in your brain) as FLUMAZENIL B. BRAUN can cause an increased pressure in your brain
- if you suffer from liver disease. Your doctor will carefully adjust the dosage of FLUMAZENIL B. BRAUN
- if you have experienced panic attacks in the past as FLUMAZENIL B. BRAUN can cause new attacks
- if you are very nervous about having your operation or have a history of anxiety. Your doctor will carefully adjust the dosage of FLUMAZENIL B. BRAUN

- if you have been treated for long periods with high doses of benzodiazepines as there is a risk of withdrawal symptoms (Withdrawal symptoms are listed in section 4. "Possible side effects")
- if you are dependent on alcohol or medicines. In this case you have a higher risk of benzodiazepine tolerance and dependence
- if you have a coronary heart disease. Your doctor should be informed as she / he might decide to keep you longer under sedation.

Your alertness and vital signs (like blood pressure, heart and breathing rate) will be controlled for an adequate period of time after you received FLUMAZENIL B. BRAUN. As the action of Flumazenil is usually shorter than that of benzodiazepines, sedation may recur. You will be closely observed, possibly in the intensive care unit, until the effects of FLUMAZENIL B. BRAUN have gone away.

If FLUMAZENIL B. BRAUN 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.

Your doctor will consider that postoperative pain may occur after major surgery before giving you FLUMAZENIL B. BRAUN**.**

If you do not wake up after FLUMAZENIL B. BRAUN is administered, another reason for this will be considered because FLUMAZENIL B. BRAUN specifically reverses the effects of benzodiazepines.

Your doctor will avoid rapid injection of FLUMAZENIL B. BRAUN**.** If you have received long-term (chronic) treatment with benzodiazepines, rapid injection of high doses of FLUMAZENIL B. BRAUN (more than 1 mg) may cause withdrawal symptoms.

FLUMAZENIL B. BRAUN is not recommended for the treatment of benzodiazepine-dependence or benzodiazepines-withdrawal symptoms.

Your doctor will administer FLUMAZENIL B. BRAUN only with particular caution in case of mixed intoxications with benzodiazepines and certain types of other antidepressants (so called cyclic antidepressants like Imipramin, clomipramin, mirtazapine or mianserin). The toxicity of these antidepressants can be masked by protective benzodiazepine effects (see also section 2 "Other medicines and Flumazenil"). Signs of a significant overdose with cyclic antidepressants include:

- dilation of the pupil, inability to urinate, dry mouth, severe or potentially life threatening conditions like agitation, breathing problems, convulsions, heart problems and coma.

Other medicines and FLUMAZENIL B. BRAUN

Always tell your health care provider if you are taking any other medicines (This includes all complimentary or traditional medicines).

Flumazenil counteracts the effect of all medicines that act via the benzodiazepine receptor. This includes medicines that do not belong to the group of benzodiazepines, but that have the same active principle such as zopiclone (like zimovane), triazolopyridazine and others.

Benzodiazepines can mask the toxic effects of certain psychotropic medicines (especially tricyclic antidepressants like Imipramin, see also section 2 “Warnings and precautions”). When using Flumazenil in cases of an accidental overdose it has to be taken into account that the toxic effects of such medicines taken concurrently may increase with the subsidence of the benzodiazepine effect.

Interaction with other central nervous system depressants or alcohol has not been observed.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, please consult your doctor or pharmacist or health care provider for advice before taking this medicine.

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

It is not known whether FLUMAZENIL B. BRAUN is excreted in breast milk. Therefore you should not breastfeed for 24 hours after administration of FLUMAZENIL B. BRAUN.

Fertility

No data available.

Driving and using machines

After receiving FLUMAZENIL B. BRAUN for the reversal of the sedative effects of benzodiazepines you must not drive a car, operate machinery or engage in any other physically or mentally demanding activity for at least 24 hours since sedation may possibly recur.

FLUMAZENIL B. BRAUN contains sodium

This medicine contains 3,7 mg of sodium per mL.

3. How to use FLUMAZENIL B. BRAUN

Do not share medicines prescribed for you with any other person.

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

If you are given more FLUMAZENIL B. BRAUN than you should

Since a health care provider will administer FLUMAZENIL B. BRAUN, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If FLUMAZENIL B. BRAUN has not been given to you

Since a health care provider will administer FLUMAZENIL B. BRAUN, it is unlikely that the dose will be missed.

4. POSSIBLE SIDE EFFECTS

FLUMAZENIL B. BRAUN can have side effects.

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

The following side effects may be serious. If any of the following happens, stop using this medicine and tell your doctor immediately or go to the casualty department at your nearest hospital:

Frequent:

- abnormal rapid and deep respiration (hyperventilation)
- speech disorder.

Less Frequent:

- slow or rapid heart rate, premature beat of your heart (extrasystole)
- difficulty in breathing
- chest pain.

Frequency Not known:

- convulsions (in patients suffering from epilepsy or severe liver insufficiency, mainly after long-term treatment with benzodiazepines or multiple medicinal products abuse)
- allergic reactions, including severe allergic response-related reactions (anaphylaxis), may occur.

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

Tell your doctor if you notice any of the following:

Other side effects include:

Frequent :

- agitation (after rapid injection, not requiring treatment)
- having problems in initiating and maintaining sleep (insomnia), feeling sleepy (somnolence)
- dizziness, headache
- involuntary trembling or quivering (tremor)
- dry mouth
- sensations on the skin (e.g. cold, warmth, tingling, pressure, etc.) in the absence of stimulation (paresthesia)
- double vision, squinting (strabismus)
- increased production of tear fluid (increased lacrimation)
- sweating
- low blood pressure, drop of blood pressure on transition from lying to standing (orthostatic hypotension)
- feeling sick: vomiting (after surgery), hiccups
- fatigue
- pain at the injection site.

Less frequent:

- anxiety and fear (occurring after rapid injection, not requiring treatment)
- being aware of your heart rate (palpitations, occurring after rapid injection, not requiring treatment)
- abnormal hearing
- cough, nasal congestion
- reddening of the skin
- shivering.

Frequency Not known:

- panic attacks in patients that already showed panic reactions
- transient increased blood pressure (on awaking)
- emotional lability
- abnormal crying, agitation and aggressive reactions
- reddening of the skin.

If you were treated for a long period with benzodiazepines, Flumazenil can induce withdrawal symptoms (frequency not known). The symptoms include: agitation, anxiety, emotional lability, confusion and abnormal sensory perception.

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, or pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://primaryreporting.who-umc.org/ZA. By reporting side effects, you can help provide more information on the safety of FLUMAZENIL B. BRAUN.

5. How to store FLUMAZENIL B. BRAUN.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label after “EXP.” The expiry date refers to the last day of that month.

Store at or below 25 °C.

This medicinal product is for single use only.

Shelf life after first opening: the medicinal product should be used immediately.

Shelf life after dilution: 24 hours.

Chemical and physical in-use stability has been demonstrated for 24 hours at 25 °C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

The solution should be inspected visually prior to use. Do not use FLUMAZENIL B. BRAUN if the solution is not clear, colourless 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). Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What FLUMAZENIL B. BRAUN contains

The active substance is flumazenil.

Each mL contains 0,1 mg flumazenil.

FLUMAZENIL 5 ML B. BRAUN**:**

Each ampoule with 5 mL contains 0,5 mg flumazenil.

FLUMAZENIL 10 ML B. BRAUN**:**

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

The other ingredients are disodium edetate, glacial acetic acid, sodium chloride, sodium hydroxide solution 4 % and water for injections.

What FLUMAZENIL B. BRAUN looks like and contents of the pack

It is a clear and colourless, solution for injection. It comes in colourless glass ampoules.

Following packaging sizes are available:

FLUMAZENIL 5 ML B. BRAUN**:**

Carton boxes with 5 or 10 ampoules containing 5 mL solution.

FLUMAZENIL 10 ML B. BRAUN**:**

Carton boxes with 5 or 10 ampoules containing 10 mL solution

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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FLUMAZENIL 10 ML B. BRAUN - 49/34/0216

The SAHPRA approved professional information can be accessed through https://pi-pil-repository.sahpra.org.za/.