PATIENT INFORMATION LEAFLET

Flumazenil 100 micrograms/ml Solution for Injection and infusion

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do NOT pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

In this leaflet:
1. What Flumazenil Injection is and what it is used for
2. Before you are given Flumazenil Injection
3. How Flumazenil Injection is given
4. Possible side effects
5. Storing Flumazenil Injection
6. Further information

1. WHAT FLUMAZENIL INJECTION IS AND WHAT IT IS USED FOR

Your doctor has decided to give you Flumazenil Injection because it reverses the effects of medicines called benzodiazepines (such as diazepam, midazolam, temazepam), which are sometimes used to cause deep sleep. Flumazenil Injection is used:
- to reverse the sleepiness you experience from a general anaesthetic after some diagnostic tests and operations.
- in intensive care patients who are on artificial ventilators. By reversing the effects of benzodiazepines, it allows the person to begin breathing without the help of ventilators.

Flumazenil is a solution given by a slow, single injection or slow continuous injection (infusion) into a vein. It works rapidly although the effects may wear off within a few hours and you may fall asleep again.

2. BEFORE YOU ARE GIVEN FLUMAZENIL INJECTION

You should not be given Flumazenil Injection if:
- You are allergic or have had any reactions to flumazenil or benzodiazepines.
- You are allergic or have had any reactions to any of the other ingredients in the injection (these are listed in Section 6, Further information).
- You suffer from epilepsy (fits/convulsions) and have been taking benzodiazepines for a long time.
- You have been taking benzodiazepines and certain antidepressants (such as amitriptyline, imipramine, dothiepin hydrochloride) at the same time.
- You are taking benzodiazepines to control a possibly life threatening condition (such as very severe epilepsy or raised pressure in the brain).

If you are unsure about any of these, ask your doctor.

3. HOW FLUMAZENIL INJECTION IS GIVEN

Flumazenil Injection will be given only under the supervision of an experienced doctor.
- Flumazenil is given by slow injection through a vein into the bloodstream over 15 seconds.
- Your dose will depend on the operation or procedure you have received and the level of sedation. This dose can be repeated every 60 seconds until the correct level of consciousness is reached.
If you become drowsy again, you may be given a slow, continuous injection (infusion) into a vein until the correct level of consciousness is reached.

- The treatment ends when you become fully awake.
- The effects of flumazenil may wear off quickly and you may need repeat doses.
- You should remain under close medical supervision until all drowsiness has gone.

**Adults and the elderly:**
Flumazenil Injection is suitable for adults including the elderly. Your doctor will calculate the dose of Flumazenil Injection and how long you will need to be treated.

**Adolescents and Children:**
Flumazenil may be used in adolescents and children above one year old.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Flumazenil Injection can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions although serious allergic reactions are very rare. Any hives (slightly raised, itchy, skin patches that are paler or redder than the surrounding skin), sudden swelling of the hands, feet, ankles, or swelling of the face, lips, mouth or throat, which may cause difficulty swallowing or breathing, should be reported to a doctor immediately.

- Flumazenil can occasionally cause nausea (feeling sick), vomiting (being sick) and a feeling of warmth or flushing.
- Flumazenil may cause you to become agitated, anxious or fearful but this is generally if you are awakened too quickly.
- Intensive care patients may have increases in blood pressure and heart rate. These effects usually disappear quickly without any treatment.
- Very rarely, flumazenil can cause seizures (fits), particularly if you suffer from epilepsy or severe liver disease.

**Withdrawal symptoms**
If you have received treatment with benzodiazepines you may experience withdrawal symptoms such as anxiety attacks, dizziness, sweating and a rapid heart rate even if you stopped taking the benzodiazepines in the weeks before flumazenil was given. Your doctor may treat such symptoms with a slow injection into the vein of medicines known as diazepam or midazolam.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

5. HOW TO STORE FLUMAZENIL INJECTION
Keep out of the reach and sight of children. Do not use Flumazenil Injection after the expiry date which is printed on the label and carton. Your medicine should be stored below 30°C. Your doctor, pharmacist or nurse will know how to store Flumazenil Injection properly.

6. FURTHER INFORMATION
What Flumazenil Injection contains
- The active ingredient is flumazenil
- The other ingredients are ethylenediamine tetraacetic acid, glacial acetic acid, sodium chloride, sodium hydroxide and water for injection.

What Flumazenil Injection looks like and contents of the pack:
Flumazenil Injection is available in 5ml and 10ml ampoules. The 5ml ampoule contains 500 micrograms of flumazenil, and the 10ml ampoule contains 1mg of flumazenil.

Marketing Authorisation Holder:
Bowmed Limited, Unit 2, Eastman Way, Stevenage, Herts SG1 4SZ, U.K.

Manufacturer:
Combio Pharm S.L., C/ Fructuós Gelabert 6-8, 08970 Sant Joan Despi - Barcelona, Spain.

Date of last revision 01/2013.

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INFORMATION FOR THE HEALTHCARE PROFESSIONAL

The following information is intended for medical or healthcare professionals only.

Instructions for use and handling:
Flumazenil 100 micrograms/ml may be diluted with Sodium Chloride Intravenous Infusion BP or Dextrose 5% Intravenous Infusion BP.
Chemical and physical stability has been demonstrated for 24 hours at room temperature.

Flumazenil 100 micrograms/ml should be administered within 3 hours of preparation.

No preparations other than those recommended should be added to the Flumazenil ampoule or mixed with the Flumazenil infusion solution.

For single use only. Discard any unused contents.

Storing Flumazenil Injection:
Store below 30°C.
The product should be used immediately after opening.
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- You are taking benzodiazepines to control a possibly life threatening condition (such as very severe epilepsy or raised pressure in the brain).

If you are unsure about any of these, ask your doctor.

Before you are given Flumazenil Injection you should tell your doctor if:

- You have a head injury.
- You suffer from or have in the past suffered from anxiety, or are very anxious about your operation.
- You suffer from heart disease, epilepsy (fits/convulsions) or severe liver disease.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines. This includes any that you may have bought without a prescription. This is extremely important because some medicines can strengthen or weaken the effect of others.

It is especially important to tell your doctor if you are taking zopiclone (to help you sleep) or antidepressants.

Pregnancy and breast-feeding

You MUST TELL your doctor if:

- you are pregnant, you think you are pregnant or you are likely to become pregnant. Your doctor will decide if you should be given this medicine.
- you are breast-feeding. Small amounts of this medicine may pass into breast milk. The medicine should be avoided except in an emergency. Your doctor will advise.

Driving and using machines

You should not drive or operate machinery or do physical or mental work for 24 hours after receiving this medicine. Ask your doctor if you are unsure.

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Continued overleaf...
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