NAME OF THE MEDICINAL PRODUCT

Flumazenil B. Braun 0.1 mg/ml solution for injection

COMPOSITION

1 ml contains 0.1 mg flumazenil.
1 ampoule with 5 ml contains 0.5 mg flumazenil.
1 ampoule with 10 ml contains 1 mg flumazenil.

Excipients:
Sodium 3.7 mg / ml.
Disodium edetate, glacial acetic acid, sodium chloride, sodium hydroxide solution 4% for pH adjustment, water for injections.

THERAPEUTIC INDICATIONS

Adults
Flumazenil is indicated for the complete or partial reversal of the central sedative effects of benzodiazepines. It may therefore be used in anaesthesia and in the intensive care in the following situations:

In anaesthesia
Termination of hypnosedative effects in general anaesthesia induced and/or maintained with benzodiazepines in hospitalized patients.
Reversal of benzodiazepine sedation in short-term diagnostic and therapeutic procedures in ambulatory patients and hospitalized patients.

In intensive care situations
For the specific reversal of the central effects of benzodiazepines, in order to restore spontaneous respiration.
For diagnosis and treatment of intoxications or overdose with only or mainly benzodiazepines.

Paediatric population
Flumazenil is indicated for the reversal of conscious sedation induced with benzodiazepines in children > 1 year of age.

CONTRAINDICATIONS

Hypersensitivity to flumazenil or to any of the excipients.

Patients receiving benzodiazepines for control of a potentially life-threatening condition (e.g. control of intracranial pressure or status epilepticus).

UNDESIRABLE EFFECTS

The adverse events listed below have been reported. Adverse events usually subside rapidly without the need for special treatment.

Undesirable effects are listed according to their frequencies as follows:

Common: (≥ 1/100 to < 1/10)
Uncommon: (≥ 1/1 000 to < 1/100)
Not known: (cannot be estimated from the available data)

System organ class

Immune systems disorders
Not known: Allergic reactions, including anaphylaxis, may occur

Psychiatric disorders
Common: Insomnia, somnolence
Uncommon: Anxiety*, fear*
Not known: Withdrawal symptoms (e.g., agitation, anxiety, emotional lability, confusion, sensory distortions), following rapid injection of doses of 1 mg or more in patients with high-dose and/or long-term exposure to benzodiazepines ending at any time within the weeks preceding flumazenil administration; panic attacks (in patients with a history of panic reactions); abnormal crying, agitation, aggressive reactions

Nervous system disorders
Common: Vertigo, headache, agitation*, tremor, dry mouth, hyperventilation, speech disorder, paresthesia
Not known: Seizures, particularly in patients known to suffer from epilepsy or severe hepatic impairment, mainly after long-term treatment with benzodiazepines or in case of mixed-drug overdose

Eye disorders
Common: Diplopia, strabismus, lacrimation increased

Ear and labyrinth disorders
Uncommon: Abnormal hearing

Cardiac disorders
Uncommon: Palpitations*, tachycardia or bradycardia, extrasystole

Vascular disorders
Common: Hypotension, orthostatic hypotension
Not known: Transient increased blood pressure (on awakening)

Respiratory, thoracic and mediastinal disorders
Uncommon: Dyspnoea, cough, nasal congestion, chest pain

Gastrointestinal disorders
Common: Nausea and vomiting during post-operative use, particularly if opiates have also been used, hiccup

Skin and subcutaneous tissue disorders
Common: Sweating
Not known: Flushing

General disorders and administration site conditions
Common: Fatigue, injection site pain
Uncommon: Shivering*

*after rapid injection, not requiring treatment

Paediatric population
In general the undesirable effect profile in children is generally similar to that in adults. When using flumazenil for the reversal of conscious sedation abnormal crying, agitation and aggressive reactions have been reported.

WARNINGS

Keep out of reach and sight of children.

NOTE

Prescription only
Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

B. Braun Melsungen AG, 34209 Melsungen, Germany, 04/2014

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Document Control
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