Easy-to-see features right on the package

Labels are DistinctIV™
- Easy-to-read drug name and strengths
- Unique label design

Cartons are InformatIV™
- Full-color cartons that coordinate with the vial labels
- Distinct label and cap color for each strength
- LATEX-FREE and bar coded

FLUMAZENIL Injection, USP

Please see full prescribing information, including boxed warning, for FLUMAZENIL Injection, USP, enclosed.
FLUMAZENIL Injection, USP

Innovator Product Name: ROMAZICON®
(Romazicon is a registered trademark of Hoffmann-La Roche Inc.)

<table>
<thead>
<tr>
<th>NDC Number</th>
<th>Description</th>
<th>Strength</th>
<th>Fill Volume</th>
<th>Concentration</th>
<th>Closure</th>
<th>Unit of Sale</th>
<th>Bar Coded</th>
</tr>
</thead>
<tbody>
<tr>
<td>25021-600-05</td>
<td>Glass Vial</td>
<td>0.5 mg</td>
<td>5 mL</td>
<td>0.1 mg per mL</td>
<td>13 mm</td>
<td>10 Vials</td>
<td>✔️</td>
</tr>
<tr>
<td>25021-600-10</td>
<td>Glass Vial</td>
<td>1 mg</td>
<td>10 mL</td>
<td>0.1 mg per mL</td>
<td>13 mm</td>
<td>10 Vials</td>
<td>✔️</td>
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</tbody>
</table>

This SAGENT product meets stringent FDA requirements and is AP rated and LATEX-FREE.

To order, or for more information about discovering Injectables Excellence™ with SAGENT, contact your sales representative, call 1-866-625-1618 or visit www.SagentPharma.com.

**FLUMAZENIL Injection, USP**

**INDICATIONS AND USAGE**

- Flumazenil Injection, USP is indicated in adult patients for the complete or partial reversal of the sedative effects of benzodiazepines in cases where general anesthesia has been induced and/or maintained with benzodiazepines, where sedation has been produced with benzodiazepines for diagnostic and therapeutic procedures, and for the management of benzodiazepine overdose.

- Flumazenil Injection, USP is indicated in pediatric patients aged 1 to 17 for the reversal of conscious sedation induced with benzodiazepines.

**IMPORTANT SAFETY INFORMATION**

**THE USE OF FLUMAZENIL HAS BEEN ASSOCIATED WITH THE OCCURRENCE OF SEIZURES.**

**THESE ARE MOST FREQUENT IN PATIENTS WHO HAVE BEEN ON BENZODIAZEPINES FOR LONG-TERM SEDATION OR IN OVERDOSE CASES WHERE PATIENTS ARE SHOWING SIGNS OF SERIOUS CYCLIC ANTIDEPRESSANT OVERDOSE.**

**PRACTITIONERS SHOULD INDIVIDUALIZE THE DOSAGE OF FLUMAZENIL AND BE PREPARED TO MANAGE SEIZURES.**

**CONTRAINDICATIONS**

Flumazenil Injection, USP is contraindicated:

- in patients with a known hypersensitivity to flumazenil or benzodiazepines.
- in patients who have been given a benzodiazepine for control of a potentially life threatening condition (e.g., control of intracranial pressure or status epilepticus).
- in patients who are showing signs of serious cyclic antidepressant overdose.

**WARNINGS AND PRECAUTIONS**

- The reversal of benzodiazepine effects may be associated with the onset of seizures in certain high-risk populations. Possible risk factors for seizures include: concurrent major sedative-hypnotic drug withdrawal, recent therapy with repeated doses of parenteral benzodiazepines, myoclonic jerking or seizure activity prior to flumazenil administration in overdose cases, or concurrent cyclic antidepressant poisoning.
- Most convulsions associated with flumazenil administration require treatment and have been successfully managed with benzodiazepines, phenytoin or barbiturates.
- Patients who have received flumazenil for the reversal of benzodiazepine effects should be monitored for resedation, respiratory depression, or other residual benzodiazepine effects for an appropriate period (up to 120 minutes) based on the dose and duration of effect of the benzodiazepine employed. Flumazenil has not been shown to be effective for the treatment of hypventilation due to benzodiazepine administration.
- Overdose cases should always be monitored for resedation until the patients are stable and resedation is unlikely.
- The availability of flumazenil does not reduce the risks associated with the use of large doses of benzodiazepines for sedation.
- Flumazenil should be used with caution in the ICU because of the increased risk of unrecognized benzodiazepine dependence in such settings. Flumazenil may produce convulsions in patients physically dependent on benzodiazepines.
- In the treatment of benzodiazepine overdose, flumazenil is intended as an adjunct to, not as a substitute for, proper management of airway, assisted breathing, circulatory access and support, internal decontamination by lavage and charcoal, and adequate clinical evaluation.
- Flumazenil should be used with caution in patients with head injury as it may be capable of precipitating convulsions or altering cerebral blood flow in patients receiving benzodiazepines.
- If neuromuscular blocking agents have been used, flumazenil should not be used until the effects of neuromuscular blockade have been fully reversed.
- The primary treatment of patients with serious lung disease who experience serious respiratory depression due to benzodiazepines should be appropriate ventilatory support rather than the administration of flumazenil.
- The clearance of flumazenil is reduced to 40% to 60% of normal in patients with mild to moderate hepatic disease and to 25% of normal in patients with severe hepatic dysfunction. Repeat doses of flumazenil in liver disease should be reduced in size or frequency.
- Flumazenil should be used with caution in patients with alcoholism and other drug dependencies due to the increased frequency of benzodiazepine tolerance and dependence observed in these patient populations.
- The safety and efficacy of flumazenil in the reversal of conscious sedation in pediatric patients below the age of 1 year have not been established.
- Pregnancy: There are no adequate and well-controlled studies of the use of flumazenil in pregnant women. Flumazenil should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**ADVERSE REACTIONS**

- The most common adverse reactions reported during clinical trials were dizziness, vomiting, agitation, injection site pain, increased sweating, headache, and abnormal or blurred vision.
- Serious adverse events including convulsions, death, and cardiac dysrhythmia have occurred. Flumazenil administration has been associated with the onset of convulsions in patients with severe hepatic impairment and in patients who are relying on benzodiazepine effects to control seizures, are physically dependent on benzodiazepines, or who have ingested large doses of other drugs. The majority of deaths occurred in patients with serious underlying disease or in patients who had ingested large amounts of non-benzodiazepine drugs, as part of an overdose.

**OVERDOSAGE**

There is limited experience of acute overdose with flumazenil, and there is no specific antidote. Treatment of an overdose with flumazenil should consist of general supportive measures including monitoring of vital signs and observation of the clinical status of the patient.

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