FRESENIUS KABI
caring for life

NEW

NAPPI code

300646700 | Pack quantity: 5

Flumazenil 0,5 mg/5 ml Fresenius

Therapeutic indications

FLUMAZENIL FRESENIUS is indicated for the reversal of the sedative effects of benzodiazepines in cases where general anaesthesia 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.

Shelf life
- 3 years

Shelf life after first opening
- After first opening the medicine should be used immediately

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

  From a microbial point of view the product should be used immediately once diluted.
  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.

Special precautions for storage
- Store at or below 25 °C. **Do not freeze.**
- Keep the ampoules in the outer carton in order to protect from light.

Reversal of general anaesthesia in adult patients:

For the reversal of the sedative effects of benzodiazepines administered for general anaesthesia, the recommended initial dose of **FLUMAZENIL FRESENIUS** is 0,2 mg (2 mL) administered intravenously over 15 seconds.

If the desired level of consciousness is not obtained after waiting an additional 45 seconds, a further dose of 0,2 mg (2 mL) can be injected and repeated at 60-second intervals where necessary (up to a maximum of 4 additional times) to a maximum total dose of 1 mg (10 mL). The dosage should be individualised based on the patient's response, with most patients responding to doses of 0,6 mg to 1 mg.

In the event of re-sedation, repeated doses may be administered at 20-minute intervals as needed. For repeat treatment, no more than 1 mg (given as 0,2 mg/min) should be administered at any one time, and no more than 3 mg should be given in any one hour.

It is recommended that **FLUMAZENIL FRESENIUS** be administered as the series of small injections described (not as a single bolus injection) to allow the practitioner to control the reversal of sedation to the approximate endpoint desired and to minimise the possibility of adverse effects.

Special warnings and precautions for use

Patients who have received FLUMAZENIL FRESENIUS for the reversal of benzodiazepine effects (after conscious sedation or general anaesthesia) should be monitored for re-sedation, 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. Because patients with hepatic impairment may experience delayed effects as described above, an extended observation period may be required.

Method of Administration:

FLUMAZENIL FRESENIUS is recommended for intravenously administration only.

To minimise the likelihood of pain at the injection site, **FLUMAZENIL FRESENIUS** should be administered through a freely running intravenous infusion into a large vein.

For instructions on dilution of the medicine before administration refer to the approved professional information.
If **FLUMAZENIL FRESENIUS** is drawn into a syringe or mixed with any of the solutions, it should be discarded after 24 hours.

It may be used concomitantly with other resuscitative measures.

FLUMAZENIL FRESENIUS should be inspected visually for particulate matter and discolouration prior to administration, whenever solution and container permit.

S5 Flumazenil 0,5 mg/5 ml Fresenius. Each 5 ml ampoule contains 0,5 mg flumazenil. Reg No.: 46/34/0063

For full prescribing information refer to professional information approved by the South African Health Products Regulatory Authority.

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