



MONOGRAPH

FLUMAZENIL

Scope (Staff):	Medical, Pharmacy, Nursing, Anaesthetic Technicians
Scope (Area):	All Clinical Areas Perth Children's Hospital (PCH)

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this [DISCLAIMER](#)

QUICKLINKS

Dosage/Dosage Adjustments	Administration	Compatibility	Monitoring
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DRUG CLASS

Benzodiazepine antidote.¹

INDICATIONS AND RESTRICTIONS

- Reversal of benzodiazepine sedation in procedural sedation and anaesthesia.¹
- Benzodiazepine overdose or intoxication.^{1, 2}

CONTRAINDICATIONS

- Hypersensitivity to flumazenil or any component of the formulation.³
- Patients using benzodiazepines for the control of potentially life-threatening conditions (e.g. control of intracranial pressure or status epilepticus).²⁻⁴

PRECAUTIONS

- Hypersensitivity to benzodiazepines^{2,4}
- Use of flumazenil in mixed overdoses of benzodiazepines and proconvulsant drugs (e.g. tricyclic antidepressants, chloral hydrate, theophylline, antihistamines, amphetamines) – may result in uncontrollable seizures and death.¹

- Patients with benzodiazepine dependence – may result in rapid reversal of benzodiazepine effects and precipitate severe withdrawal symptoms and seizures.^{1, 3}
- Patients with head injuries, unstable intracranial pressure (ICP) – may cause convulsions, raised ICP or alter cerebral blood flow.^{1, 3}
- Flumazenil is not to be administered until the effects of neuromuscular blockers have been fully reversed.^{2, 3}
- Patients with epilepsy who have received benzodiazepines for prolonged periods – may increase risk of seizures.³
- Patients treated with benzodiazepines for anxiety or panic disorder – may precipitate anxiety or panic attack.²

FORMULATIONS

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- 500 microgram / 5 mL ampoule.

Imprest location: [Formulary One](#)

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Refer to [Neonatal Medication Protocols](#)

Children and adolescents (4 weeks to 18 years):

- Intermittent IV: 5 – 10 microg/kg (maximum 200 microg) administered over 15 seconds.^{4,5}
 - If response is inadequate, repeat dose every 60 seconds to a maximum of 50 microg/kg (usual maximum 1 mg; children > 12 years old in Paediatric Critical Care may use maximum 2 mg).⁵
- A continuous IV infusion may be commenced if drowsiness recurs after IV injection.³
- Continuous IV infusion⁵:
 - 40 kg and below: 2 – 10 micrograms/kg/hour; adjust according to response.
 - Above 40 kg: 100 – 400 micrograms/hour; adjust according to response.
- If a bolus dose is required at the commencement of the continuous IV infusion, it may be administered via the infusion pump using the standard concentration syringe:
 - Bolus dose 40 kg and below: 5 microg/kg
 - Bolus dose above 40 kg: 100 to 200 microg

Renal impairment:

- No dosage adjustment required.^{2, 4}

Hepatic impairment:

- No adjustment necessary for the initial dose. For repeat doses, reduce the dose or frequency.^{2, 4}

ADMINISTRATION

- **IV injection:** Administer undiluted over 15 seconds, into a free-flowing IV infusion line into a large vein to minimise pain and phlebitis at injection site.^{6, 7} Dose may also be diluted to an appropriate volume with a compatible fluid and injected.²
- **Continuous IV infusion:**
 - Dilute 1 mg up to a total volume of 50 mL with a compatible fluid.
- Do not administer if particulate matter is present or if the solution is discoloured.²
- Avoid extravasation.²

COMPATIBILITY (LIST IS NOT EXHAUSTIVE)

Compatible fluids:

Glucose 5%; Hartmann's solution; sodium chloride 0.9%.^{2, 6, 7}

[Compatibilities of IV drugs](#) must be checked when two or more drugs are given concurrently.

INCOMPATIBLE drugs: Limited data available; check with pharmacy or avoid concurrent administration with other medications.

MONITORING

- Level of consciousness and sedation, blood pressure, heart rate, respiratory rate, continuous pulse oximetry.⁴
- Observe for reoccurrence of sedation and hypoventilation for at least 2 hours (4 hours in hepatic impairment) post-dose as the half-life of flumazenil is much shorter than that of all benzodiazepines.^{1, 3, 4}
- Observe for benzodiazepine withdrawal symptoms such as anxiety, agitation, confusion, seizures.¹

ADVERSE EFFECTS

Common: Nausea, vomiting, dizziness, headache, agitation, fatigue, blurred vision, injection site reaction,^{1, 2}

Rare: Seizures, cardiac arrhythmias.⁴

Withdrawal symptoms or anxiety may also occur, relating to reversal of the benzodiazepine.³

STORAGE

- Store below 25 °C in a cool dry place.³

INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. [Clinical Pharmacology](#)), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

Please note: The information contained in this guideline is to assist with the preparation and administration of flumazenil. Any variations to the doses recommended should be clarified with the prescriber prior to administration




Related CAHS internal policies, procedures, and guidelines

[Withdrawal Syndrome Management \(health.wa.gov.au\)](https://www.health.wa.gov.au/withdrawal-syndrome-management)

References

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2. Flumazenil pediatric monograph [Internet]. Philadelphia (PA): Elsevier Inc.; 2023 [cited 2023 Nov 06]. Available from: Clinical Pharmacology powered by ClinicalKey.
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4. Lexicomp Editorial Advisory Panel. Flumazenil pediatric drug information [Internet]. Waltham (MA): Lexicomp Inc.; 2023 [cited 2023 Nov 13]. Available from: UpToDate.
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6. The Royal Children's Hospital Melbourne. Flumazenil. 2023 [cited 2023 Dec 01]. In: Paediatric Injectable Guidelines Online [Internet]. Melbourne (VIC): The Royal Children's Hospital Melbourne. 9th edition. [cited 2023 Dec 01]. Available from: <https://pig-rch-org-au.pklibresources.health.wa.gov.au/monographs/flumazenil/>.
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