KETAMINE INTERPHARMA

ketamine hydrochloride 250mg/5mL
ketamine hydrochloride 100mg/10mL

NOW AVAILABLE
The first prediluted ketamine solutions

250mg in 5mL glass ampoule

100mg in 10mL glass ampoule

- First available prediluted ketamine ampoule solutions in Australia
- Facilitating dose standardisation
- Improved convenience and safety of administration
- Reduced risk of diversion
- 25% more ketamine per ampoule vs contrentrate (250mg/5mL)
- Made in Austria

InterPharma

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www.interpharma.com.au

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ketamine hydrochloride 250mg/5mL
ketamine hydrochloride 100mg/10mL

Active Ingredient	Ketamine hydrochloride
Excipients	Water for injections, Hydrochloric Acid, Sodium Hydroride (pH adjustment)
Immediate Container	colourless glass ampoules
Pack Size	Presented in packs of 5 x 5mL (250mg) and 5 x 10mL (100mg) clear glass ampoules
Stability Unopened	3 years, store below 30°C

Please review full production before prescribing. Full product information is available from:
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2019- PI-02404-1

MINIMUM PRODUCT INFORMATION: KETAMINE HYDROCHLORIDE
QUALITATIVE AND QUANTITATIVE COMPOSITION: KETAMINE INTERPHARMA is formulated as an acid (pH 3.5 to 5.5) solution for IV injection in concentrations containing the equivalent of 10 mg/mL or 50 mg/mL ketamine base. **THERAPEUTIC INDICATIONS:** KETAMINE INTERPHARMA is recommended as the sole anaesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation. Best suited for short procedures and can be used with additional doses, for longer procedures. Can also be used for the induction of anaesthesia prior to the administration of other general anaesthetic agents and to supplement low-potency agents such as nitrous oxide. **DOSE AND METHOD of ADMINISTRATION:** For single use in one patient only. All doses are given in terms of ketamine base. As with other general anaesthetic agents, the individual response to KETAMINE INTERPHARMA is somewhat varied depending on the dose, route of administration and age of patient, so that the dosage recommended cannot be absolutely determined in a fixed manner. The drug should be titrated against the patient's requirements. For further information refer to the FULL PI. **CONTRAINDICATIONS:** Patients with any condition in which a significant elevation of blood pressure would be hazardous such as: severe cardiovascular disease, heart failure, severe or poorly controlled hypertension, recent myocardial infarction, history of stroke, cerebral trauma, intracerebral mass or haemorrhage. Ketamine is also contraindicated in those who have shown hypersensitivity to the drug or its components. **SPECIAL WARNINGS AND PRECAUTIONS FOR USE** - KETAMINE INTERPHARMA should be used by or under direction of medical practitioners experienced in administering general anaesthetics and in maintenance of an airway and in the control of respiratory support. Barbiturates and Ketamine being chemically incompatible because of precipitate formation, should not be injected from the same syringe. Prolonged recovery time may occur if barbiturates and/or narcotics are used concurrently with KETAMINE INTERPHARMA. Because pharyngeal and laryngeal reflexes are usually active, KETAMINE INTERPHARMA should not be used alone in surgery or diagnostic procedures of the pharynx, larynx or bronchial tree. Use in caution in patients with: - increased intraocular pressure (eg. glaucoma); neurotic traits or psychiatric illness; acute intermittent porphyria; seizures; hyperthyroidism or patients receiving thyroid replacement (increased risk of hypertension and tachycardia); pulmonary or upper respiratory infection (ketamine sensitises the gag reflex, potentially causing laryngospasm); intracranial mass lesions, a presence of head injury, globe injuries, or hydrocephalus. Use in pregnancy- Category B3. Please refer to full PI for full list of special warnings and precautions for use. **ADVERSE EFFECTS (UNDESIRABLE EFFECTS):** Adverse effects have been observed under the following clinical system organ class – cardiovascular, respiration, eye, psychologic al, neurological, gastrointestinal, immune system, abuse potential. Please refer to Full PI for full list of adverse effects. Report any suspected adverse reactions at www.tga.au/reporting-problems. **OVERDOSE:** Respiratory depression may occur with overdosage or too rapid rate of administration of KETAMINE INTERPHARMA, in which case, supportive ventilation should be employed. Mechanical support of respiration is preferred to administration of analeptics. Ketamine has a wide margin of safety; several instances of unintentional administration of overdoses of KETAMINE INTERPHARMA (up to 10 times that usually required) have been followed by prolonged but complete recovery.
For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).
PHARMACEUTICAL PARTICULARS – List of excipients – water for injections. 10mg/mL preparations have saline added to achieve isotonicity. **Incompatibilities:** barbiturates- due to precipitate formation, should not be injected from the same syringe. **Special precautions for storage:** Store below 30°C. Protect from light. KETAMINE INTERPHARMA should not be used if the solution is coloured and/or contains particulate matter. **NATURE AND CONTENTS OF CONTAINER:** Presented in glass ampoules in packs of 5. KETAMINE INTERPHARMA 10 mg/mL is available in sizes 20mg/2 mL (AUST R 310918), 50mg/5 mL (AUST R 310910), 100mg/10mL (AUST R 310913). KETAMINE INTERPHARMA 50mg/mL is available in sizes 100mg/2mL (AUST R310914), 250mg/5mL (AUST R 310912), 500 mg/10mL (AUST R 310916). Not all strengths may be marketed.

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