Ketamine Hydrochloride Injection USP 50mg/ml

Composition :

Each ml contains :

Ketamine Hydrochloride USP Equivalent to Ketamine	50 mg
Benzethonium Chloride USP (As preservative)	0.01% w/v
Water for Injections BP	q.s.

PHARMACOLOGY :

DESCRIPTION :

Ketamine hydrochloride is a nonbarbiturate anesthetic chemically designated (±)-2-(o-Chlorophenyl)-2-(methylamino) cyclohexanone hydrochloride. It is formulated as a slightly acid (pH 3.5-5.5) sterile solution for intravenous or intramuscular injection in concentrations containing the equivalent of 50 mg ketamine base per milliliter and contains not more than 0.1 mg/mL benzethonium chloride added as a preservative.

It has the following molecular formula $C_{13}H_{16}ClNO$ HCl with a molecular weight of 274.19.

Mechanism of Action :

Ketamine blocks nerve paths without depressing respiratory and circulatory functions, and therefore acts as a safe and reliable anaesthetic.

PHAMACOKINETICS :

INDICATIONS AND USAGE

Ketamine hydrochloride injection is indicated as the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation. Ketamine hydrochloride injection is best suited for short procedures but it can be used, with additional doses, for longer procedures.

Ketamine hydrochloride injection is indicated for the induction of anesthesia prior to the administration of other general anesthetic agents.

Ketamine hydrochloride injection is indicated to supplement low-potency agents, such as nitrous oxide.

DOSAGE AND ADMINISTRATION :

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Note : Barbiturates and ketamine, being chemically incompatible because of precipitate formation, should not be injected from the same syringe.

If the ketamine dose is augmented with diazepam, the two drugs must be given separately. Do not mix ketamine hydrochloride and diazepam in syringe or infusion flask. For additional information on the use of diazepam, refer to the **WARNINGS** and **DOSAGE AND ADMINISTRATION** sections of the diazepam insert.

Preoperative Preparations :

1. While vomiting has been reported following ketamine administration, some airway protection may be afforded because of active laryngeal-pharyngeal reflexes. However, since aspiration may occur with ketamine and since protective reflexes may also be diminished by supplementary anesthetics and muscle relaxants, the possibility of aspiration must be considered. Ketamine is recommended for use in the patient whose stomach is not empty when, in the judgement of the practitioner, the benefits of the drug outweigh the possible risks.

2. Atropine, scopolamine, or another drying agent should be given at an appropriate interval prior to induction.

Onset and Duration

Because of rapid induction following the initial intravenous injection, the patient should be in a supported position during administration.

The onset of action of ketamine is rapid; an intravenous dose of 2 mg/kg (1 mg/lb) of body weight usually produces surgical anesthesia within 30 seconds after injection, with the anesthetic effect usually lasting five to ten minutes. If a longer effect is desired, additional increments can be administered intravenously or intramuscularly to maintain anesthesia without producing significant cumulative effects.

Intramuscular doses, from experience primarily in children, in a range of 9 to 13 mg/kg (4 to 6 mg/lb) usually produce surgical anesthesia within 3 to 4 minutes following injection, with the anesthetic effect usually lasting 12 to 25 minutes.

Dosage :

As with other general anesthetic agents, the individual response to ketamine is somewhat varied depending on the dose, route of administration, and age of patient, so that dosage recommendation cannot be absolutely fixed. The drug should be titrated against the patient's requirements.

Intravenous Route: The initial dose of ketamine administered intravenously may range from 1 mg/kg to 4.5 mg/kg (0.5 to 2 mg/lb). The average amount required to produce five to ten minutes of surgical anesthesia has been 2 mg/kg (1 mg/lb).

Alternatively, in adult patients an induction dose of 1 mg to 2 mg/kg intravenous ketamine at a rate of 0.5 mg/kg/mm may be used for induction of anesthesia. In addition, diazepam in 2 mg to 5 mg doses, administered in a separate syringe over 60 seconds,

may be used. In most cases, 15 mg of intravenous diazepam or less will suffice. The incidence of psychological manifestations during emergence, particularly dream-like observations and emergence delirium, may be reduced by this induction dosage program.

Route of Administration: It is recommended that ketamine be administered slowly (over a period of 60 seconds). More rapid administration may result in respiratory depression and enhanced pressor response.

Intramuscular Route: The initial dose of ketamine administered intramuscularly may range from 6.5 to 13 mg/kg (3 to 6 mg/lb). A dose of 10 mg/kg (5 mg/lb) will usually produce 12 to 25 minutes of surgical anesthesia.

CONTRA INDICATIONS :

Ketamine is contraindicated in those in whom a significant elevation of blood pressure would constitute a serious hazard and in those who have shown hypersensitivity to the drug.

ADVERSE REACTION :

Cardiovascular : Blood pressure and pulse rate are frequently elevated following administration of ketamine alone. However hypotension and bradycardia have been observed. Arrhythmia has also occurred.

Respiration : Although respiration is frequently stimulated, severe depression of respiration or apnea may occur following rapid intravenous administration of high doses of ketamine. Laryngospasms and other forms of airway obstruction have occurred during ketamine anesthesia.

Eye : Diplopia and nystagmus have been noted following ketamine administration. It also may cause a slight elevation in intraocular pressure measurement.

Psychological : Neurological In some patients, enhanced skeletal muscle tone may be manifested by tonic and clonic movements sometimes resembling seizures (see DOSAGE AND ADMINISTRATION).

Gastrointestinal : Anorexia, nausea and vomiting have been observed; however, this is not usually severe and allows the great majority of patients to take liquids by mouth shortly after regaining consciousness (see DOSAGE AND ADMINISTRATION).

General : Local pain and exanthema at the injection site have infrequently been reported. Transient erythema and/or morbilliform rash have also been reported.

PREGNANCY : Since the safe use in pregnancy, including obstetrics (either vaginal or abdominal delivery), has not been established, such use is not recommended

DRUG INTERACTIONS :

Prolonged recovery time may occur if barbiturates and/or narcotics are used concurrently with ketamine.

Ketamine is clinically compatible with the commonly used general and local anesthetic agents when an adequate respiratory exchange is maintained.

OVER DOSE :

Respiratory depression may occur with overdosage or too rapid a rate of administration of ketamine, in which case supportive ventilation should be employed. Mechanical support of respiration is preferred to administration of analeptics.

WARNINGS :

Cardiac function should be continually monitored during the procedure in patients found to have hypertension or cardiac decompensation.

Postoperative confusional states may occur during the recovery period.

Respiratory depression may occur with overdosage or too rapid a rate of administration of ketamine, in which case supportive ventilation should be employed. Mechanical support of respiration is preferred to administration of analeptics.

PRESENTATION :

Available in glass Ampoule

STORAGE :

Store below 30°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN

Manufactured by:

SWISS PARENTERALS LTD.

Ahmedabad, Gujarat, INDIA.

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