

# KETAMINE HYDROCHLORIDE INJECTION USP

## Composition:

Each ml contains:

Ketamine Hydrochloride USP

Equivalent to Ketamine .....50mg

Benzyl Alcohol USP (as preservative).....2% v/v

Water for injection B.P. ....q.s.

## DESCRIPTION

Ketamine HCl injection is a nonbarbiturate anesthetic sterile solution for intravenous or intravenous or intramuscular injection in concentrations containing the equivalent of either 10, 50 or 100 mg ketamine base per milliliter and contains not more than 0.1 mg/ml Phemerol® (benzethonium chloride) added as a preservative. The 10 mg/ml solution has been made isotonic with sodium chloride.

## CLINICAL PHARMACOLOGY

Ketamine HCl injection is a rapid-acting general anesthetic producing an anesthetic state characterized by profound analgesia, normal pharyngeal-laryngeal reflexes, normal or slightly enhanced skeletal muscle tone, cardiovascular and respiratory stimulation, and respiratory depression.

## INDICATIONS AND USAGE

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

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

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

## CONTRAINDICATIONS

Ketamine hydrochloride 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.

## 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. (See Special Note) Respiratory depression may occur with overdosage or too rapid a rate administration of Ketamine HCl Injection, in which case supportive ventilation should be employed. Mechanical support of respiration is preferred to administration of analeptics.

## ADVERSE REACTIONS

Cardiovascular: Blood pressure and pulse rate are frequently elevated following administration of Ketamine HCl injection 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 HCl injection. Laryngospasms and other forms of airway obstruction have occurred during Ketamine HCl injection anesthesia.

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

Neurological: In some patients, enhanced skeletal muscle tone may be manifested by tonic and clonic movements sometimes resembling seizures

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

General: Anaphylaxis Local pain and exanthema at the injection site have infrequently been reported.

Transient erythema and/ or morbilliform rash have also been reported.

For medical advice about your adverse reactions contact your medical professional.

## DOSAGE

As with other general anesthetic agents, the individual response to ketamine HCl injection 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.

**STORAGE:** Store at 20°- 25°C. Protect from light.

**PRESENTATION:** 10 ML Vial

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