Ketalar
(Ketamine Hydrochloride Injection, USP)

DESCRIPTION
Ketalar is a nonbarbiturate anesthetic chemically designated 2-(0-chlorophenyl)-2-(methylamino) cyclohexanone hydrochloride. It is formulated as a slightly acidic (pH 3.5–5.5) sterile solution for 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 Phenergan (promazine hydrochloride) added as a preservative. The 10 mg/mL solution has been made isotonic with sodium chloride.

CLINICAL PHARMACOLOGY
Ketalar is a rapid-acting general anesthetic producing an anesthetic state characterized by profound analgesia, normal pharynx-larynx-oesophageal reflexes, normal or slightly enhanced skeletal muscle tone, cardiovascular and respiratory stability, and occasional transient and minimal respiratory depression. A patient is maintained partly by virtue of unimpaired pharynx and laryngeal reflexes. (See WARNINGS AND PRECAUTIONS.)

Manufactured and Distributed by:
Pfizer Global Supply Life Sciences, LLC
600 Warren Street
Rochester, MI 48307

Manufactured and Distributed by:
PharmaPAC, LLC
14006 SW 77th Court
Miami, FL 33183

SPECIAL NOTE
EMERGENCE REACTIONS HAVE OCCURRED IN APPROXIMATELY 12 PERCENT OF PATIENTS. THE PSYCHOLOGICAL MANIFESTATIONS, IF PRESENT, DIFFER FROM THE IDENTITY OF DREAMS, IN COLOUR, INTENSITY, AND EVENTS KNOWN TO THE PATIENT. THE PSYCHOLOGICAL MANIFESTATIONS OF PATIENTS UNDER THE INFLUENCE OF KETALAR (Ketamine Hydrochloride Injection, USP) DO NOT MEET THE CRITERIA OF A DREAM STATE, SUCH AS IN COLOUR, INTENSITY, AND EVENTS KNOWN TO THE PATIENT.

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The intravenous dose should be administered over a period of 60 seconds. More rapid administration may result in a loss of control of respiration. Use with caution in the chronically alcoholic and the acutely intoxicated patient. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, for dose selection, especially for patients with history of cerebrovascular disease, it is recommended that a dose of 1 mg/kg be administered over a period of 60 seconds. Beginning with a dose of 1 mg/kg, the dosage should be titrated to effect based on patient response.

Onset and Duration: The onset of action of Ketalar 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, 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 Ketalar is somewhat variable depending on the dose, route of administration, and the patient's condition. Dosage recommendations cannot be absolutely fixed. The drug should be titrated against the patient's requirements.

Induction: Intravenous Route: The initial dose of Ketalar administered intravenously may range from 1 mg/kg to 4 mg/kg (0.5 mg/lb 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/min may be used to produce induction of anesthesia. In addition, icapem 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 icapem or 25 mg of intravenous diazepam may achieve this objective. The incidence of psychological manifestations during emergence, particularly dream-like observations and emergence delirium, may be reduced by this induction dosage program.

Note: The 100 mg/ml concentration of Ketalar should not be injected intravenously without proper dilution. It is recommended that 100 mg/ml Ketalar be diluted with an equal volume of either Sterile Water for Injection, USP, or 5% Dextrose in Water. Rate of Administration: It is recommended that Ketalar be administered slowly (over a period of 60 seconds).

Intramuscular Route: The initial dose of Ketalar 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) usually produce 12 to 25 minutes of surgical anesthesia.

Maintenance of Anesthesia: The maintenance dose of Ketalar should be adjusted according to the patient’s anesthetic needs and whether an additional anesthetic agent is employed. Increments of one-half to the full induction dose may be required as needed for maintenance anesthesia. However, it should be noted that profound and tophoric movements of extremities should not occur and these should not imply a light plane and are not indicative of the need for additional doses of the anesthetic. It should be recognized that the larger the total dose of Ketalar administered, the longer will be the duration of anesthesia.

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Preparation of Solution for Intravenous Use: Ketalar is compatible with the commonly used general anesthetic agents. When Ketalar is used in combination with other anesthetics, it is preferable to administer the induction dose for the induction of anesthesia prior to the administration of other general anesthetic agents. Ketalar is indicated as the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation. Ketalar is contraindicated in those in whom a significant elevation of blood pressure has been described following discontinuation of long-term ketamine use. Therefore, ketamine should not be used in patients in whom a significant elevation of blood pressure has been described following discontinuation of long-term ketamine use. Therefore, ketamine should not be used in patients

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