FREEDOM OF INFORMATION (FOI) SUMMARY

Ketamine Hydrochloride injection for cats and subhuman primates

ANADA 200-257

Vetrepharm Research, Inc.
119 Rowe Road
Athens, Georgia 30601
1. **GENERAL INFORMATION**

**ANADA #:** 200-257

**Sponsor:**
Vetrepharm Research, Inc.
119 Rowe Road
Athens, GA, U.S.A.
30601
DLC # 064847

**Trade Name:** Ketamine HCl

**Generic Name:** Ketamine hydrochloride injection USP

**Dosage Form:** Sterile Solution

**How Supplied:** 10 ml multiple doses vials

**How Dispensed:** Prescription

**Amount of Active Ingredients:** Each ml contains ketamine hydrochloride equivalent to 100-mg ketamine base.

**Route of Administration:** Intramuscular Injection

**Species:** Cats and subhuman primates

**Labeled Dosage:**

- **Cats:**
  
  A dose of 11 mg/kg (5 mg/lb) is recommended to produce restraint. Dosages from 22 to 33 mg/kg (10 to 15 mg/lb) produce anesthesia that is suitable for diagnostic or minor surgical procedures that do not require skeletal muscle relaxation.

- **Subhuman primates:**
  
  The recommended restraint dosages for the following species are: *Cercococcus torquatus* (white-collared mangabey), *Papio cynocephalus* (yellow baboon), *Pan troglodytes verus* (chimpanzee), *Papio anubis* (olive baboon), *Pongo pygmaeus* (orangutan), *Macaca nemestrina* (pig-tailed macaque), 5 to 7.5 mg/kg; *Presbytis entellus* (entellus langur), 3 to 5 mg/kg; *Gorilla gorilla gorilla* (gorilla), 7 to 10
mg/kg; *Aotus trivirgatus* (night monkey), 10 to 12 mg/kg; *Macaca mulatta* (rhesus monkey), 5 to 10 mg/kg; *Cebus capucinus* (white-throated capuchin), 13 to 15 mg/kg; *Macaca fascicularis* (crab-eating macaque), *Macaca radiata* (bonnet macaque), and *Saimiri sciureus* (squirrel monkey), 12 to 15 mg/kg.

A single intramuscular injection produces restraint suitable for TB testing, radiography, physical examination or blood collection.

**Indications for Use:**

Ketamine hydrochloride injection, USP may be used in cats for restraint or as the sole anesthetic agent for diagnostic or minor, brief, surgical procedures that do not require skeletal muscle relaxation. It may be used in subhuman primates for restraint.

**Pioneer Product:**

*Vetalar®,* (ketamine hydrochloride, 100 mg/mL), NADA 045-290 by Fort Dodge Animal Health.

2. **TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:**

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (53 FR 50460, December 15, 1988, first GADPTRA Policy Letter), an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). For certain dosage forms, the Agency grants a waiver from conducting an in vivo bioequivalence study (55 FR 24645, June 18, 1990; fifth GADPTRA Policy Letter). In lieu of bioequivalence testing, the safety and efficacy of the generic product are based on the demonstrated chemical equivalence to the pioneer product.

Based on the formulation characteristics of the generic product, Vetrepharm Research, Inc. was granted a waiver February 6, 1998, from conducting an in vivo bioequivalence study with Ketamine Hydrochloride Injection. The generic and pioneer products are solutions with the same inactive ingredients and the same concentrations of the active ingredient.

3. **HUMAN SAFETY:**

**Human Safety Relative to Food Consumption:**

Regarding consumption of drug residues in food, human safety data are not required since this drug is labeled for use in cats and subhuman primates not intended for food.

**Human Safety Relative to Possession, Handling and Administration:**

Labeling contains adequate caution/warning statements.
4. AGENCY CONCLUSIONS:

This is an Abbreviated New Animal Drug Application (ANADA) filed under Section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act.

Safety and effectiveness for this generic animal drug, Ketamine Hydrochloride Injection (100 mg/ml), were established by demonstration of chemical equivalence to the pioneer product, Fort Dodge Animal Health's Vetalar® (ketamine hydrochloride, USP, 100 mg/ml, NADA 045-290).

This generic product and the pioneer product have identical labeling indications for use. The route and method of administration of the two drugs are identical. Both drugs are administered by intramuscular injection. The generic and pioneer products are both solutions that contain the same active and inactive ingredients in the same concentrations. Both products have the same pH. Therefore, in compliance with FDA policy promulgated to implement Section 512(b)(2) of the FFD&C Act, no additional safety, efficacy, or in vivo bioequivalency studies were necessary or required.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Ketamine HCl is safe and effective for its labeled indications when used under its proposed conditions of use.
KETAMINE HCl CO
Ketamine HCI inj., USP
Equivalent to
100 mg/mL Ketamine
45 mL
CAUTION:
Remove resealable vial from the drug to use by or at the order of a licensed veterinarian.
ANADA 280-257
Approved by FDA

Distributed by:
Veterepharm Research, Inc.
Atlanta, GA, U.S.A. 30301

For intramuscular use
Store at room temperature
15.30°C (59-86°F).
Protect from light.

DOSAGE:
See package insert.
For Use in Cats and
Subhuman Primates Only.
Not more than 2.1 mg/mL
sodium metabisulfite
added as a preservative.
Color of solution may vary
darken upon prolonged
exposure to light. This
darkening does not affect
potency. Do not use if
discoloration appears.
KETAMINE HCl @
Ketamine HCl inj., USP
Equivalent to 100 mg/mL Ketamine 10 mL
CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
AMADA 200251
Approved by FDA

For Intramuscular Use
DOSAGE: See package insert.
For use in Cats and Subhuman Primates Only.
Store at room temperature 15-30°C (59-86°F).
Protect from light.
Color of solution may vary from colorless to very slightly yellowish and may darken upon prolonged exposure to light. This darkening does not affect potency. Use only if precipitate appears.
Not more than 0.1 mg/mL benzethonium chloride added as a preservative.

Distributed by:
Veterepharm Research, Inc.
Athens, GA U.S.A. 30601
KETAMINE HCl
KETAMINE HYDROCHLORIDE INJECTION, USP

Veterinary Injection for Intramuscular Use in Cats and Subhuman Primates Only

DESCRIPTION
KETAMINE HCl is a racemic, heterocyclic, nonsteroidal agent for anesthetic use in cats and for restraint in subhuman primates. It is chemically designated d/2-(o-chlorophenyl)-2-(methylamino) cyclohexanone hydrochloride and is supplied as a slightly acid (pH 3.5 - 5.5) solution for intramuscular injection in a concentration containing the equivalent of 100 mg ketamine base per milliliter and contains not more than 0.1 mg barbituric acid as a preservative.

ACTION
KETAMINE HCl is a rapid-acting agent whose pharmacologic action is characterized by profound angesia, normal pharyngeal-laryngeal reflexes, mild cardiac stimulation and respiratory depression. Skeletal muscle tone is variable and may be normal, enhanced or diminished. The anesthetic state produced does not fit into the conventional classification of stages of anesthesia, but instead KETAMINE HCl produces a state of unconsciousness which has been termed "disassociative" anesthesia in that it appears to selectively interrupt association pathways to the brain before producing somesthetic sensory blockade.

In contrast to other anesthetics, respiration usually remains intact, although the respiration rate is usually decreased. The assurance of a patent airway is greatly enhanced by virtue of maintained pharyngeal-laryngeal reflexes. Although some salivation is occasionally noted, the persistence of the swallowing reflex aids in minimizing the hazards associated with aspiration. Salivation may be effectively controlled with atropine sulfate in dosages of 0.04 mg/kg (0.02 mg/lb) in cats and 0.01 to 0.05 mg/kg (0.005 to 0.025 mg/lb) in subhuman primates.

Other reflexes, e.g., comat, pedal, etc. are maintained under KETAMINE HCl anesthesia. The degree of muscle tone is dependent upon level of dose; therefore, variations in body temperature may occur. At low dose levels there may be an increase in muscle tone and a concomitant slight increase in body temperature. However, at high dose levels there is some diminution in muscle tone and a resultant decrease in body temperature, to the point where supplemental heat may be advisable.

In cats, there is usually some transient cardiovascular stimulation, increased cardiac output with slight increase in mean systolic pressure with little or no change in total peripheral resistance. At higher doses, the respiratory rate is usually decreased. However, at high dose levels there is some diminution in muscle tone and a resultant decrease in body temperature, to the point where supplemental heat may be advisable.

Intramuscular injection produces restraint suitable for TB testing, radiography, or minor, brief, surgical procedures that do not require skeletal muscle relaxation. It may be used in subhuman primates for restraint.

CONTRAINDICATIONS
KETAMINE HCl is contraindicated in cats and subhuman primates suffering from renal or hepatic insufficiency.

KETAMINE HCI is dose-fatigue by the liver and excreted by the kidneys; therefore, any preexistent hepatic or renal pathology or impairment of function can be expected to result in prolonged anesthesia; related fatalities have been reported.

PRECAUTIONS
In cats, doses in excess of 50 mg/kg during any single procedure should not be used. The maximum recommended dose in subhuman primates is 40 mg/kg.

To reduce the incidence of emergence reactions, animals should not be stimulated by sound or handling during the recovery period. However, this does not preclude the monitoring of vital signs.

Apnea, respiratory arrest, cardiac arrest and death have occasionally been reported with ketamine used alone, and more frequently when used in conjunction with sedatives or other anesthetics. Close monitoring of patients is strongly advised during induction, maintenance and recovery from anesthesia.

ADVERSE REACTIONS
Respiratory depression may occur following administration of high doses of KETAMINE HCl. If at any time respiration becomes excessively depressed and the animal becomes cyanotic, resuscitative measures should be instituted promptly. Adequate pulmonary ventilation using either oxygen or room air is recommended as a resuscitative measure.

Adverse reactions reported include emesis, salivation, vocalization, erections and prolonged recovery, episodic jerking movements, convulsions, muscular tremors, hypertension, apnea, hypotension, dyspnea and cardiac arrest. In the cat, myoclonic jerking and/or datale twitching can be controlled by ultrashort-acting barbiturates which should be given to the patient. The procedure should be arranged using an additive dose of one sixth to one eighth the usual dose for the species. Anesthesia may also be used. However, recent information indicates that some phenothiazine derivatives may potentiate the toxic effects of agents, such as pentobarbital and the results of their use in certain anesthetics. A study has indicated that ketamine hydrochloride alone does not potentiate the toxic effects of organic phosphate compounds.

ADMINISTRATION AND DOSAGE
KETAMINE HCl is well tolerated by cats and subhuman primates when administered by intramuscular injection.

Fasting prior to induction of anesthesia or restraint with KETAMINE HCl is not essential; however, when preparing for elective surgery, it is advisable to withhold food for at least six hours prior to administration of KETAMINE HCl.

Anesthesia may be of shorter duration in immature cats. Restraint in subhuman primates requires more frequent injections. Doses in excess of 50 mg/kg during any single procedure should not be used. The maximum recommended dose in subhuman primates is 40 mg/kg.

Subhuman Primates: The recommended restraint doses of KETAMINE HCl for the following species are: Cercocebus torquatus (white-collared mangabey) Papio cynocephalus (yellow baboon). Pongo pygmaeus (orangutan), Macaca nemestrina (pig-tailed macaque) 5 to 7.5 mg/kg. *Presbytis entellus (entellus langur) 3 to 5 mg/kg; *Cercopithecus galeritus (patas monkey) 5 to 10 mg/kg. *Macropus eugenii (emu) 5 to 10 mg/kg; *Cebus capucinus (white-throated capuchin) 10 to 15 mg/kg. *Presbytis melalophus (spectacled leaf monkey) 2 to 5 mg/kg; *Presbytis barbata (barbata monkey) 5 to 10 mg/kg. *Cebus capucinus (white-throated capuchin) 10 to 15 mg/kg and selected subspecies of *Cercopithecus *Monge (mango monkey) 12 to 15 mg/kg.

A single intramuscular injection produces restraint suitable for TB testing, radiography, physical examination and blood collection.

HOW SUPPLIED
KETAMINE HCl is supplied as the hydrochloride in concentrations equivalent to ketamine base. Each 10 ml vial contains 100 mg/ml. NDC 5484-637-034-10 - 10 ml - vial.

CLINICAL STUDIES
KETAMINE HCl has been clinically studied in subhuman primates in addition to those species listed under Administration and Dosage. Dosages for restraint in those additional species, based on limited clinical data, are: Cercocebus atys (guenon) Papio papio (guinea baboon) 10 to 12 mg/kg; *Rhinopithecus luteolus (golden lion tamarin) 5 to 10 mg/kg; *Saimiri sciureus (squirrel monkey) 10 to 15 mg/kg; *Cebus capucinus (white-throated capuchin) 10 to 15 mg/kg; Macaca fascicularis* (Japanese macaque) 5 mg/kg; *Macaca fascicularis (stumptailed macaque) and *Presbytis entellus (entellus langur) 5 to 7.5 mg/kg.

*Ketamine is supplied in the United States as Ketamine HCl Injection, Hydrochloride for Intravenous Use, USP, 100 mg/ml. Ketamine HCl is also available as Ketamine HCl Injection, Hydrochloride for Intramuscular Use, USP, 100 mg/ml. Ketamine HCl is also available as Ketamine HCl Injection, Hydrochloride for Intraosseous Use, USP, 100 mg/ml. Ketamine HCl is also available as Ketamine HCl Injection, Hydrochloride for Intranasal Use, USP, 100 mg/ml.

Distributed by:
Vetapharm
Athens, GA U.S.A. 30601

Textonomy from "A Handbook of Living Primates" by Napior and Napior, Academic Press, New York, N.Y.
For Intramuscular Use

Store at controlled room temperature 15° to 30°C (59° to 86°F). Protect from light.

**DOSAGE:** See package insert.

For use in cats and subhuman primates only.

Not more than 0.1 mg/mL benzethonium chloride added as a preservative.

Color of solution may vary from colorless to very slightly yellowish and may darken upon prolonged exposure to light. This darkening does not affect potency. Do not use if precipitate appears.

See bottom flap for lot number and expiration date.
Ketaset®
KETAMINE HCl INJ., USP

For Intramuscular Use

DOSAGE: See package insert.

For Use in Cats and Subhuman Primates Only.

Store at controlled room temperature 15° to 30°C (59° to 86°F). Protect from light.

Not more than 0.1 mg/mL benzethonium chloride added as a preservative.

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA
4401G

NDC 0856-2013-01
Equivalent to
100 mg/mL Ketamine
10 mL

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
NADA 45-290, Approved by FDA
Ketaset<sup>®</sup> II
KETAMINE HYDROCHLORIDE INJECTION, USP

Veterinary Injection For Intramuscular Use in Cats and Subhuman Primates Only

**CAUTION**

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Color of solution may vary from colorless to very slightly yellowish and may darken upon prolonged exposure to light. This darkening does not affect potency. Do not use if precipitate appears.

Not more than 0.1 mg/mL benzethonium chloride added as a preservative.

**DESCRIPTION**

KETASET (ketamine hydrochloride Injection, USP) is a rapid-acting, nonnarcotic, nonbarbiturate agent for anesthetic use in cats and for restraint in subhuman primates. It is chemically designated \( d/2-(o\text{-chlorophenyl})-2-(\text{methylamino}) \) cyclohexanone hydrochloride and is supplied as a slightly acid (pH 3.5 to 5.5) solution for intramuscular injection in a concentration containing the equivalent of 100 mg ketamine base per milliliter and contains not more than 0.1 mg/mL benzethonium chloride as a preservative.

**ACTIONS**

KETASET is a rapid-acting agent whose pharmacological action is characterized by profound analgesia, normal pharyngeal-laryngeal reflexes, mild cardiac stimulation and respiratory depression. Skeletal muscle...
KETASET is a rapid-acting agent whose pharmacological action is characterized by profound analgesia, normal pharyngeal-laryngeal reflexes, mild cardiac stimulation and respiratory depression. Skeletal muscle tone is variable and may be normal, enhanced or diminished. The anesthetic state produced does not fit into the conventional classification of stages of anesthesia, but instead KETASET produces a state of unconsciousness which has been termed "dissociative" anesthesia in that it appears to selectively interrupt association pathways to the brain before producing somesthetic sensory blockade.

In contrast to other anesthetics, protective reflexes, such as coughing and swallowing are maintained under KETASET anesthesia. The degree of muscle tone is dependent upon level of dose; therefore, variations in body temperature may occur. At low dosage levels there may be an increase in muscle tone and a concomitant slight increase in body temperature. However, at high dosage levels there is some diminution in muscle tone and a resultant decrease in body temperature, to the point where supplemental heat may be advisable.

In cats, there is usually some transient cardiovascular stimulation, increased cardiac output with slight increase in mean systolic pressure with little or no change in total peripheral resistance. At higher doses the respiratory rate is usually decreased.

The assurance of a patent airway is greatly enhanced by virtue of maintained pharyngeal-laryngeal reflexes. Although some salivation is occasionally noted, the persistence of the swallowing reflex aids in minimizing the hazards associated with ptysalism. Salivation may be effectively controlled with atropine sulfate in dosages of 0.04 mg/kg (0.02 mg/lb) in cats and 0.01 to 0.05 mg/kg (0.005 to 0.025 mg/lb) in subhuman primates.

Other reflexes, e.g., corneal, pedal, etc., are maintained during KETASET anesthesia, and should not be used as criteria for judging depth of anesthesia. The eyes normally remain open with the pupils dilated. It is suggested that a bland ophthalmic ointment be applied to the cornea if anesthesia is to be prolonged.

Following administration of recommended doses, cats become ataxic in about 5 minutes with anesthesia usually lasting from 30 to 45 minutes at higher doses. At the lower doses, complete recovery usually occurs in 4 to 5 hours but with higher doses recovery time is more prolonged and may be as long as 24 hours.
doses. At the lower doses, complete recovery usually occurs in 4 to 5 hours but with higher doses recovery time is more prolonged and may be as long as 24 hours.

In studies involving 14 species of subhuman primates represented by at least 10 anesthetic episodes for each species, the median time to restraint ranged from 1.5 [Aotus trivirgatus (night monkey) and Cebus capucinus (white-throated capuchin)] to 5.3 minutes [Macaca nemestrina (pig-tailed macaque)]. The median duration of restraint ranged between 20 and 55 minutes in all but five of the species studied. Total time from injection to end of restraint ranged from 43 [Saimiri sciureus (squirrel monkey)] to 183 minutes [Macaca nemestrina (pig-tailed macaque)] after injection. Recovery is generally smooth and uneventful. The duration is dose related.

By single intramuscular injection, KETASET usually has a wide margin of safety in cats and subhuman primates. In cats, cases of prolonged recovery and death have been reported.

**INDICATIONS**

KETASET may be used in cats for restraint or as the sole anesthetic agent for diagnostic or minor, brief, surgical procedures that do not require skeletal muscle relaxation. It may be used in subhuman primates for restraint.

**CONTRAINDICATIONS**

KETASET is contraindicated in cats and subhuman primates suffering from renal or hepatic insufficiency.

KETASET is detoxified by the liver and excreted by the kidneys; therefore, any preexistent hepatic or renal pathology or impairment of function can be expected to result in prolonged anesthesia; related fatalities have been reported.

**PRECAUTIONS**

In cats, doses in excess of 50 mg/kg during any single procedure should not be used. The maximum recommended dose in subhuman primates is 40 mg/kg.

To reduce the incidence of emergence reactions, animals should not be stimulated by sound or handling during the recov-
**PRECAUTIONS** (cont'd.)

Every period. However, this does not preclude the monitoring of vital signs.

Apnea, respiratory arrest, cardio arrest and death have occasionally been reported with ketamine used alone, and more frequently when used in conjunction with sedatives or other anesthetics. Close monitoring of patients is strongly advised during induction, maintenance and recovery from anesthesia.

**ADVERSE REACTIONS**

Respiratory depression may occur following administration of high doses of KETASET (ketamine hydrochloride injection, USP). If at any time respiration becomes excessively depressed and the animal becomes cyanotic, resuscitative measures should be instituted promptly. Adequate pulmonary ventilation using either oxygen or room air is recommended as a resuscitative measure.

Adverse reactions reported have included emesis, salivation, vocalization, erratic recovery and prolonged recovery, spastic jerking movements, convulsions, muscular tremors, hyperthermia, opisthotonus, dyspnea and cardiac arrest. In the cat, myoclonic jerking and/or mild tonic convulsions can be controlled by ultrashort-acting barbiturates which should be given to effect. The barbiturates should be administered intravenously at a dose level of one-sixth to one-fourth the usual dose for the product being used. Acepromazine may also be used. However, recent information indicates that some phenothiazine derivatives may potentiate the toxic effects of organic phosphate compounds such as found in flea collars and certain anthelmintics. A study has indicated that ketamine hydrochloride alone does not potentiate the toxic effects of organic phosphate compounds.

**ADMINISTRATION AND DOSAGE**

KETASET is well tolerated by cats and subhuman primates when administered by intramuscular injection.

Fasting prior to induction of anesthesia or restraint with KETASET is not essential. However, when preparing for elective surgery, it is advisable to withhold food for at least six hours prior to administration of KETASET.

Anesthesia may be of shorter duration in immature cats. Restraint in subhuman primate neonates (less than 24 hours of age) is difficult to achieve.

As with other anesthetic agents, the in-
Anesthesia may be of shorter duration in immature cats. Restraint in subhuman primate neonates (less than 24 hours of age) is difficult to achieve.

As with other anesthetic agents, the individual response to KETASET is somewhat varied depending upon the dose, general condition and age of the subject so that dosage recommendations cannot be absolutely fixed.

**Dosage**

**Cats:** A dose of 11 mg/kg (5 mg/lb) is recommended to produce restraint. Dosages from 22 to 33 mg/kg (10 to 15 mg/lb) produce anesthesia that is suitable for diagnostic or minor surgical procedures that do not require skeletal muscle relaxation.

**Subhuman Primates:** The recommended restraint dosages of KETASET for the following species are: *Cercopithecus torquatus* (white-collared mangabey), *Papio cynocephalus* (yellow baboon), *Pongo troglodytes verus* (chimpanzee), *Papio anubis* (olive baboon), *Pongo pygmaeus* (orangutan), *Macaca nemestrina* (pig-tailed macaque) 5 to 7.5 mg/kg; *Presbytis entellus* (entellus langur) 3 to 5 mg/kg; *Gorilla gorilla gorilla* (gorilla) 7 to 10 mg/kg; *Aotus tririvirgatus* (night monkey) 10 to 12 mg/kg; *Macaca mulatta* (rhesus monkey) 5 to 10 mg/kg; *Cebus capucinus* (white-throated capuchin) 13 to 15 mg/kg; and *Macaca fascicularis* (crab-eating macaque), *Macaca radiata* (bonnet macaque) and *Saimiri sciureus* (squirrel monkey) 12 to 15 mg/kg.

A single intramuscular injection produces restraint suitable for TB testing, radiography, physical examination or blood collection.

**HOW SUPPLIED**

KETASET (ketamine hydrochloride injection, USP) is supplied as the hydrochloride in concentrations equivalent to ketamine base.

Each 10 mL vial contains 100 mg/mL.

NDC 0856-2013-01 — 10 mL — vial

**CLINICAL STUDIES**

KETASET has been clinically studied in subhuman primates in addition to those species listed under Administration and Dosage. Dosages for restraint in these additional species, based on limited clinical data, are: *Cercopithecus aethiops* (gelivet), *Papio papio* (guinea baboon) 10 to 12 mg/kg; *Erythrocebus patas patas* (patas monkey) 3 to 5 mg/kg; *Hyllobates lar* (white-handed gibbon) 5 to 10 mg/kg; *Lemur catta* (ring-tailed lemur) 7.5 to 10 mg/kg; *Macaca fuscata* (Japanese macaque) 5 mg/kg; *Macaca speciosa* (stump-tailed macaque) and *Mlopithecus*
Taxonomy from "A Handbook of Living Primates" by Napier and Napier, Academic Press, New York, N.Y.
**Ketaset®**

**KETAMINE HCl INJ., USP**

For Intramuscular Use

**DOSAGE:** See package insert.

For Use in Cats and Subhuman Primates Only.

Store at controlled room temperature 15° to 30°C (59° to 86°F). Protect from light.

Not more than 0.1 mg/mL benzethonium chloride added as a preservative.

**Equivalent to**

100 mg/mL

Ketamine

10 mL

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

NADA 45-230, Approved by FDA

**Taxonomy from "A Handbook of Living Primates" by Napier and Napier, Academic Press, New York, N.Y.**

White-handed gibbon (Nomascus leucogenys) 5 to 10 mg/kg.

Ringtailed lemur (Lemur catta) (Japanese macaque) 7.5 to 10 mg/kg.

Japanese macaque (Macaca fuscata) 7.5 mg/kg.

Stumptailed macaque (Macaca speciosa) 5 to 7.5 mg/kg.

Mangrove monkey (Makalea nemestrina) 5 to 7 mg/kg.

Ft. dodge Animal Health
Fort Dodge, Iowa 50501 USA

NDC 0756-2073-01