

Date of Approval: December 5, 2025

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-710

Maropitant Citrate

Injectable solution

Dogs and cats

Dogs: Maropitant Citrate Injectable Solution is indicated for the prevention and treatment of acute vomiting in dogs.

Cats: Maropitant Citrate Injectable Solution is indicated for the treatment of vomiting in cats.

Sponsored by:

Dechra Veterinary Products LLC

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I. GENERAL INFORMATION

A. File Number

ANADA 200-710

B. Sponsor

Dechra Veterinary Products LLC
7015 College Blvd.
Suite 525
Overland Park, KS 66211

Drug Labeler Code: 017033

C. Proprietary Name

Maropitant Citrate

D. Drug Product Established Name

maropitant citrate

E. Pharmacological Category

Antiemetic

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

Each mL contains 10 mg of maropitant as maropitant citrate.

H. How Supplied

20 mL vial

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Use of refrigerated product may reduce the pain response associated with subcutaneous injection.

Dogs:

For Prevention and Treatment of Acute Vomiting in Dogs:

Dogs 2-4 Months of Age: Administer Maropitant Citrate Injectable Solution subcutaneously at 1 mg/kg (0.45 mg/lb) equal to 0.1 mL/kg (0.1 mL/2.2 lb) of body weight once daily for up to 5 consecutive days.

Dogs 4 months of Age and Older: Administer Maropitant Citrate Injectable Solution intravenously over 1-2 minutes or subcutaneously at 1 mg/kg (0.45 mg/lb) equal to 0.1 mL/1 kg (1 mL/22 lb) of body weight once daily for up to 5 consecutive days.

In dogs that are actively vomiting, it is recommended to initiate treatment with Maropitant Citrate Injectable Solution. Thereafter, maropitant citrate tablets may be used for the prevention of acute vomiting at 2 mg/kg once daily. (See maropitant citrate tablet package insert for complete prescribing information).

For Prevention of Vomiting in Dogs 4 months of Age and Older Caused by Emetogenic Medications or Chemotherapeutic Agents: Administer Maropitant Citrate Injectable Solution intravenously over 1-2 minutes or subcutaneously at 1 mg/kg (0.45 mg/lb) of body weight one time, 45-60 minutes prior to use of emetogenic medications or chemotherapeutic agents.

Cats:

For Treatment of Vomiting in Cats 4 Months of Age and Older: Administer Maropitant Citrate Injectable Solution intravenously over 1-2 minutes or subcutaneously at 1 mg/kg (0.45 mg/lb) equal to 0.1 mL/kg (0.1 mL/2.2 lb) of body weight once daily for up to 5 consecutive days.

The underlying cause of acute vomiting should be identified and addressed in dogs and cats that receive Maropitant Citrate Injectable Solution. If vomiting persists despite treatment, the case should be re-evaluated.

K. Route of Administration

Intravenous or subcutaneous

L. Species/Class

Dogs and cats

M. Indications

Dogs: Maropitant Citrate Injectable Solution is indicated for the prevention and treatment of acute vomiting in dogs.

Cats: Maropitant Citrate Injectable Solution is indicated for the treatment of vomiting in cats.

N. Reference Listed New Animal Drug (RLNAD)

Cerenia®; maropitant citrate; NADA 141-263; Zoetis Inc.

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). The ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. Effectiveness, target animal safety and human food safety data (other than

tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food-producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Dechra Veterinary Products LLC was granted a biowaiver for the generic product Maropitant Citrate injectable solution. The generic drug product is an injectable solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is Cerenia® (maropitant citrate) injectable solution, sponsored by Zoetis Inc., under NADA 141-263, and was approved for the prevention and treatment of acute vomiting in dogs on January 29, 2007, for use in dogs 8 weeks and older and for use in cats on May 16, 2012, and for the intravenous route of administration in dogs and cats on January 11, 2016.

III. HUMAN FOOD SAFETY

This drug is intended for use in dogs and cats. Because this new animal drug is not intended for use in food-producing animals, the Food and Drug Administration (FDA) did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this ANADA.

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Maropitant Citrate:

Not for use in humans. Keep out of reach of children. In case of accidental injection or exposure, seek medical advice. Topical exposure may elicit localized allergic skin reactions in some individuals. Repeated or prolonged exposure may lead to skin sensitization. In case of accidental skin exposure, wash with soap and water. Maropitant Citrate Injectable Solution is also an ocular irritant. In case of accidental eye exposure, flush with water for 15 minutes and seek medical attention.

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the FD&C Act. The data demonstrate that Maropitant Citrate, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.