Date of Approval: June 23, 2017

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-618

Zoletil® for Injection

tiletamine HCl and zolazepam HCl

Injectable solution

Dogs and cats

In cats for restraint or for anesthesia combined with muscle relaxation and in dogs for restraint and minor procedures of short duration (30 min. avg.) requiring mild to moderate analgesia

Sponsored by:

Virbac AH, Inc.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-618

B. Sponsor

Virbac AH, Inc.
3200 Meacham Blvd.
Ft. Worth, TX 76137

Drug Labeler Code: 051311

C. Proprietary Name

Zoletil® for Injection

D. Product Established Name

tiletamine HCl and zolazepam HCl

E. Pharmacological Category

Anesthetic, Schedule III

F. Dosage Form

Injectable Solution

G. Amount of Active Ingredient

The addition of 5 mL sterile water for injection, USP results in each one mL containing 50 mg tiletamine and 50 mg zolazepam.

H. How Supplied

Individual vials of 5 mL solution when reconstituted

I. Dispensing Status

Rx

J. Dosage Regimen

Dogs: In healthy dogs, an initial intramuscular dosage of 3 to 4.5 mg/lb (6.6 to 9.9 mg/kg) Zoletil® for Injection is recommended for diagnostic purposes; 4.5 to 6 mg/lb (9.9 to 13.2 mg/kg) for minor procedures of short duration, such as treatment of lacerations and wounds, castrations and other procedures requiring mild to moderate analgesia. When supplemental doses of Zoletil® for Injection are required, such individual supplemental doses should be less than the initial dose, and the total dose given (initial dose plus supplemental dose or doses) should not exceed 12 mg/lb (26.4 mg/kg). The maximum safe dose is 13.6 mg/lb (29.92 mg/kg).

Cats: In healthy cats, an initial Zoletil® for Injection dosage of 4.4 to 5.4 mg/lb (9.7 to 11.9 mg/kg) is recommended for such procedures as dentistry, treatment of abscesses, foreign body removal and related types of surgery; 4.8 to 5.7 mg/lb (10.6 to 12.5 mg/kg) for minor procedures requiring mild to moderate analgesia, such as repair of lacerations, castrations and other procedures of short duration. Initial dosages of 6.5 to 7.2 mg/lb (14.3 to 15.8 mg/kg) are recommended for ovario-hysterectomy and onychectomy. When supplemental doses of Zoletil® for Injection are required, such individual supplemental doses should be given in increments that are less than the initial dose, and the total dose given (initial dose plus supplemental doses) should not exceed the maximum allowable safe dose of 32.7 mg/lb (72 mg/kg).

K. Route of Administration

Intramuscular injection

L. Species/Class

Dogs and cats

M. Indications

Zoletil® for Injection is indicated in cats for restraint or for anesthesia combined with muscle relaxation and in dogs for restraint and minor procedures of short duration (30 min. avg.) requiring mild to moderate analgesia.

N. Reference Listed New Animal Drug

Telazol®; tiletamine HCl and zolazepam HCl; NADA 106-111; Zoetis Inc.

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug (RLNAD)). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, 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. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal period for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of demonstrating bioequivalence (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Virbac AH, Inc. was granted a waiver from the requirement to demonstrate bioequivalence for the generic product Zoletil® for Injection (tiletamine HCl and zolazepam HCl) injectable solution. The generic drug product is an injectable solution, contains the same active ingredients 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 Telazol® (tiletamine HCl and zolazepam HCl) injectable solution, sponsored by Zoetis Inc., under NADA 106-111, and was approved for use in dogs and cats on April 9, 1982.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this approval.

V. HUMAN FOOD SAFETY:

Data on human food safety, pertaining to drug residues in food, were not required for approval of this application. This drug is approved for use in dogs and cats, which are not food producing animals.

VI. USER SAFETY:

CVM did not require user safety studies for this approval.

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Zoletil® for Injection:

FOR USE IN DOGS AND CATS ONLY.

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that Zoletil® for Injection, when used according to the label, is safe and effective.