

Date of Approval: November 25, 2020

FREEDOM OF INFORMATION SUMMARY
SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-557

Tzed™

(tiletamine and zolazepam for injection)

Injectable Solution

Dogs

Provides for a new indication, Tzed™ administered intravenously is indicated in dogs for induction of anesthesia followed by maintenance with an inhalant anesthetic, a change in the proprietary name, and a change in trade dress.

Sponsored by:

Dechra Veterinary Products LLC

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I. GENERAL INFORMATION

A. File Number

ANADA 200-557

B. Sponsor

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

Drug Labeler Code: 026637

C. Proprietary Name

Tzed™

D. Drug Product Established Name

tiletamine and zolazepam for injection

E. Drug Enforcement Agency (DEA) Schedule

Tzed™ (tiletamine and zolazepam for injection) is a nonnarcotic, nonbarbiturate dissociative and minor tranquilizing anesthetic and is a Class III controlled substance.

F. Pharmacological Category

Anesthetic, DEA Schedule Class III controlled substance

G. Dosage Form

Injectable solution

H. Amount of Active Ingredient

100 mg/mL total (equivalent to 50 mg/mL tiletamine and 50 mg/mL zolazepam)

I. How Supplied

Individual vials of 5 mL solution when reconstituted

J. Dispensing Status

Prescription (Rx)

K. Dosage Regimen

Intravenous (IV) For Induction of Anesthesia Followed by Maintenance with an Inhalant Anesthetic: In dogs, for induction of anesthesia, administer Tzed™ intravenously at 1-2 mg/lb (2.2-4.4 mg/kg) body weight to effect. Tzed™ should be administered slowly, over 30-45 seconds; after approximately 30-60 seconds, the dog's level of consciousness, muscle relaxation, and jaw tone should

be assessed to determine the ability to intubate. If after waiting 60 seconds the dog's level of anesthesia is not sufficient for successful intubation, additional Tzed™ may be administered; the total dose should not exceed 2 mg/lb (4.4 mg/kg) body weight.

L. Route of Administration

Intravenous injection

M. Species/Class

Dogs

N. Indication

Tzed™ administered intravenously is indicated in dogs for induction of anesthesia followed by maintenance with an inhalant anesthetic.

O. Reference Listed New Animal Drug

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

P. Effect of Supplement

This supplement provides for the addition of a new indication, the intravenous administration for induction of anesthesia followed by maintenance with an inhalant anesthetic in dogs, to change the proprietary name, and a change in trade dress.

II. BIOEQUIVALENCE

CVM did not require additional bioequivalence information for this supplemental approval. The FOI Summary for the original approval of ANADA 200-557, dated March 26, 2015, contains a summary of data that demonstrates bioequivalence of the drug for intravenous administration for induction of anesthesia followed by maintenance with an inhalant anesthetic in dogs.

III. HUMAN FOOD SAFETY

This drug is intended for use in dogs. Because this new animal drug is not intended for use in food-producing animals, CVM did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this supplemental ANADA.

IV. USER SAFETY

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

FOR USE IN DOGS AND CATS ONLY.

V. AGENCY CONCLUSIONS

The information submitted in support of this supplemental ANADA satisfy the requirements of section 512(c)(2) of the Federal Food, Drug, and Cosmetic Act. The

data demonstrate that Tzed™, when used according to the label, is safe and effective for the indications listed in Section I.N. above.