

Date of Approval: December 22, 2025

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-832

Robenacoxib

Tablets

Cats

Robenacoxib tablets are indicated for the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration, in cats ≥ 5.5 lbs (2.5 kg) **and** ≥ 4 months of age; for up to a maximum of 3 days.

Sponsored by:

ZyVet Animal Health, Inc.

Executive Summary

Robenacoxib tablets are approved for the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration, in cats \geq 5.5 lbs (2.5 kg) **and** \geq 4 months of age; for up to a maximum of 3 days. The reference listed new animal drug (RLNAD) is onsior™ (robenacoxib) tablets, sponsored by Elanco US Inc., under NADA 141-320. This is the first generic robenacoxib tablet for cats.

Bioequivalence

The sponsor conducted one *in vivo* blood-level study in cats to show that the 6 mg Robenacoxib tablet is bioequivalent to the 6 mg onsior™ tablet. No serious adverse events were reported during the study.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-832

B. Sponsor

ZyVet Animal Health, Inc.
73 Route 31N
Pennington, NJ 08534

Drug Labeler Code: 086117

C. Proprietary Name

Robenacoxib

D. Drug Product Established Name

robenacoxib

E. Pharmacological Category

Non-steroidal anti-inflammatory drug (NSAID)

F. Dosage Form

Tablet

G. Amount of Active Ingredient

6 mg robenacoxib per tablet

H. How Supplied

Robenacoxib tablets are available as 6 mg round flavored tablets in blisters and are supplied in blister cards containing 3 tablets. The blister cards are supplied in a veterinary carton containing 10 blister cards and are to be dispensed 1 card per patient in a Robenacoxib tablets dispensing envelope containing veterinary insert and owner information sheet, supplied with the product.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

The dose of Robenacoxib tablets is 0.45 mg/lb (1 mg/kg) orally once daily, for a maximum of 3 days. See dosing chart for dosage directions.

Dosage Directions: For oral use in cats \geq 5.5 lbs and \geq 4 months of age; for up to a maximum of 3 days. Tablets are not scored and should not be broken.

Body weight	6 mg Robenacoxib Tablets
5.5 to 13.2 lbs (2.5 to 6 kg)	1 whole tablet once daily
13.3 to 26.4 lbs (6.1 to 12 kg)	2 whole tablets once daily

Do not use in cats weighing less than 5.5 lbs, as cats less than 5.5 lbs cannot be accurately dosed.

K. Route of Administration

Oral

L. Species/Class

Cats

M. Indication

Robenacoxib tablets are indicated for the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration, in cats \geq 5.5 lbs (2.5 kg) **and** \geq 4 months of age; for up to a maximum of 3 days.

N. Reference Listed New Animal Drug

onsior™; robenacoxib; NADA 141-320; Elanco US 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 this ANADA, one *in vivo* blood-level study was conducted to demonstrate product bioequivalence using the generic and RLNAD robenacoxib 6 mg tablets in cats. The RLNAD is available in a 6 mg tablet size. The *in vivo* blood-level study was conducted in 34 healthy, fasted cats. The pivotal parameters to evaluate bioequivalence are the observed maximum plasma drug concentration (C_{MAX}) and area under the concentration-time curve (AUC) from time 0 to the last sampling time before the first unquantifiable

concentration after C_{MAX} . Bioequivalence was demonstrated between the generic 6 mg robenacoxib tablet and the RLNAD 6 mg robenacoxib tablet by the mixed reference-scaled average bioequivalence approach as described in the Statistical Methods section below. The study information is summarized below.

Blood-level Bioequivalence Study in Cats

Title: A Masked, Randomized, Four Period, Two Sequence, Single Dose Oral, Cross Over Bioequivalence Study of Robenacoxib tablets 6 mg and onsior™ (robenacoxib) Tablets 6 mg in Healthy Cats under Fasted Conditions. (Study No. 113-BF-0224)

Study Dates: September 17, 2024, to March 6, 2025

Study Locations:

In-life phase: ON, Canada

Bioanalytical testing: ON, Canada

Study Design:

Objective: The objective of this study was to determine the comparative *in vivo* blood-level bioequivalence data for the generic 6 mg robenacoxib and the RLNAD 6 mg onsior™ (robenacoxib) in fasted cats.

Study Animals: Thirty-four healthy male neutered cats between 0.74 to 4.7 years of age and weighing 3.8 to 5.7 kg.

Experimental Design: A randomized, masked, four-period, two-sequence, single-dose crossover study conducted according to Organization for Economic Cooperation and Development Principles of Good Laboratory Practice.

Drug Administration: Each animal received 6 mg of either the generic or RLNAD robenacoxib according to their randomized treatment sequence (generic/RLNAD/generic/RLNAD or RLNAD/generic/RLNAD/generic).

Measurements and Observations: The plasma concentrations of robenacoxib were measured using a validated bioanalytical method. Pharmacokinetic parameters were determined for each animal individually in each period. Animal observations were made throughout the study for assessment of general health and adverse events.

Statistical Methods:

The laboratory study was conducted as a randomized, masked four-period, two-sequence, two-treatment, single-dose crossover design using 34 healthy male cats with a 7-day washout between periods. Appropriate randomization of animal to sequence and cage/treatment order was performed. Primary variables evaluated were C_{MAX} and AUC. Time to maximum concentration (T_{MAX}) was summarized and evaluated clinically.

The reference-scaled average bioequivalence (RSABE) was used as appropriate to evaluate bioequivalence through the mixed scaling approach. Prior to the analysis, C_{MAX} and AUC values were natural logarithm transformed. The estimated within-subject

standard deviation (s_{WR}) of the RLNAD was calculated separately for transformed C_{MAX} and AUC to select the appropriate analysis approach based on FDA Guidances.

- The s_{WR} was less than 0.294 for AUC, so the average bioequivalence method was used to evaluate bioequivalence. The statistical model included fixed effects of treatment, sequence and period, and a random effect of subject nested within sequence. Period was modeled as a repeated factor. Bioequivalence was established because the back-transformed estimated upper and lower bounds of the pertinent 90% confidence interval for geometric mean ratios (generic:RLNAD) were contained within the acceptance limits of 0.80 to 1.25.
- The s_{WR} was greater than 0.294 for C_{MAX} , so the RSABE method was used, and bioequivalence was established based on the following two criteria:
 - The estimated 95% upper confidence bound for $(\mu_T - \mu_R)^2 - \theta^* \sigma_{WR}^2$ is less than zero (0), where μ_T and μ_R are the population means of the natural log transformed primary variable for the generic article and RLNAD, respectively, σ_{WR} is the population within-subject standard deviation for RLNAD, $\theta = (\log(1.25)/\sigma_{W0})^2$ and $\sigma_{W0} = 0.25$.
 - The point estimate of the generic to RLNAD geometric mean ratio is contained within the acceptance limits of 0.80 and 1.25.

Results:

As seen in the table below (Table II.1), C_{MAX} and AUC met the pre-specified criteria for bioequivalence. The mean values of T_{MAX} obtained for the generic article and RLNAD were summarized.

Table II.1. Bioequivalence Evaluation

Parameter	s_{WR}	Generic Mean	RLNAD Mean	Ratio [◇]	95% Upper Bound [§]	90% CI for the Ratio
AUC (ng/mL)*hour	0.147	3024 [†]	3108 [†]	0.97	NE	0.92, 1.02
C_{MAX} (ng/mL)	0.370	2057	2294	0.90	-0.057	NE
T_{MAX} (hours) (SD) [‡]	NE	1.42 (1.01) [‡]	1.18 (1.03) [‡]	NE	NE	NE

[†] Geometric mean

[‡] Arithmetic mean and standard deviation (SD)

[◇] Ratio = Test/Reference

[§] 95% upper confidence bound for $(\mu_T - \mu_R)^2 - \theta^* \sigma_{WR}^2$

CI = confidence interval

NE = not estimated

Adverse Reactions:

There were no serious adverse events reported during the study.

Conclusion:

The *in vivo* bioequivalence study demonstrated that the generic 6 mg robenacoxib tablets and the RLNAD 6 mg onsior™ (robenacoxib) tablets are bioequivalent in cats.

III. HUMAN FOOD SAFETY

This drug is intended for use in cats. 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 ANADA.

IV. USER SAFETY

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

Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans. **For oral use in cats only.**

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 Robenacoxib, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.