

Date of Approval: March 9, 2026

# FREEDOM OF INFORMATION (FOI) SUMMARY

## ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-804

Robenacoxib Injection

(robenacoxib)

Injectable Solution

Dogs and Cats

**Dogs:** Robenacoxib Injection is indicated for the control of postoperative pain and inflammation associated with soft tissue surgery in dogs  $\geq$  4 months of age; for up to a **maximum of 3 days**.

**Cats:** Robenacoxib Injection is indicated for the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration in cats  $\geq$  4 months of age; for up to a maximum of 3 days.

Sponsored by:

Cronus Pharma Specialities India Private Ltd.

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**I. GENERAL INFORMATION**

**A. File Number**

ANADA 200-804

**B. Sponsor**

Cronus Pharma Specialities India Private Ltd.  
Plot No.9(B), Survey No. 99/1, GMR Hyderabad Aviation SEZ Ltd.,  
Mamidipalle Village, Balapur Mandal, Shamshabad, Rangareddy,  
Hyderabad, Telangana, 500108, India

Drug Labeler Code: 069043

U.S. Agent Name and Address:

Jodi Beaudry, MSc  
J<sup>2</sup> Consulting LLC  
45 Bugling Elk Ln  
Columbus, MT 59019

**C. Proprietary Name**

Robenacoxib Injection

**D. Drug Product Established Name**

robenacoxib

**E. Pharmacological Category**

Non-steroidal anti-inflammatory drug (NSAID)

**F. Dosage Form**

Injectable solution

**G. Amount of Active Ingredient**

20 mg/mL

**H. How Supplied**

20 mL multidose vial

**I. Dispensing Status**

Prescription (Rx)

**J. Dosage Regimen**

**Dogs:**

The dose of Robenacoxib Injection is 0.91 mg/lb (2 mg/kg) subcutaneously once daily, for a **maximum of 3 days**.

For subcutaneous injection in dogs  $\geq 4$  months of age; for up to a **maximum of 3 days**. The first dose should be administered approximately 45 minutes prior to surgery, at the same time as the pre-anesthetic agents are given.

Subsequent doses can be given via subcutaneous injection, or interchanged with the oral tablet in dogs  $\geq 5.5$  lbs **and**  $\geq 4$  months of age, for a maximum of 3 total robenacoxib doses over 3 days, not to exceed one dose per day. If subsequent doses are given by subcutaneous injection, different sites for each injection should be used.

**Cats:**

The dose of Robenacoxib Injection is 0.91 mg/lb (2 mg/kg) subcutaneously once daily, for a maximum of 3 days.

For subcutaneous injection in cats  $\geq 4$  months of age; for up to a maximum of 3 days. To ensure accuracy of dosing, the use of a 1 mL graduated syringe is recommended. The first dose should be administered approximately 30 minutes prior to surgery, at the same time as the pre-anesthetic agents are given.

Subsequent doses can be given via subcutaneous injection, or interchanged with the oral tablet in cats  $\geq 5.5$  lbs **and**  $\geq 4$  months of age, for a maximum of 3 total robenacoxib doses over 3 days, not to exceed one dose per day.

**Note: In cats, the dose of robenacoxib tablets and Robenacoxib Injection are different.**

**K. Route of Administration**

Subcutaneous injection

**L. Species**

Dogs and cats

**M. Indications**

**Dogs:** Robenacoxib Injection is indicated for the control of postoperative pain and inflammation associated with soft tissue surgery in dogs  $\geq 4$  months of age; for up to a **maximum of 3 days**.

**Cats:** Robenacoxib Injection is indicated for the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration in cats  $\geq 4$  months of age; for up to a maximum of 3 days.

**N. Reference Listed New Animal Drug (RLNAD)**

onsior™; robenacoxib; NADA 141-443; 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 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, Cronus Pharma Specialities India Private Ltd. was granted a biowaiver for the generic product Robenacoxib Injection (robenacoxib). 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 onsior™ (robenacoxib) injection, sponsored by Elanco US Inc., under NADA 141-443, and was approved for use in cats on August 5, 2015, and in dogs on November 16, 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 Robenacoxib Injection:

Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental exposure to humans, including accidental ingestion or injection by humans. **For subcutaneous use in dogs and 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 Injection, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.