

Date of Approval: September 20, 2023

**FREEDOM OF INFORMATION SUMMARY**  
**SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION**

ANADA 200-310

estroPLAN®

(cloprostenol injection)

Injectable solution

Lactating dairy cows

Provides for the addition of the indication "For use with gonadorelin to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows".

Sponsored by:

Parnell Technologies Pty. Ltd.

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**I. GENERAL INFORMATION**

**A. File Number**

ANADA 200-310

**B. Sponsor**

Parnell Technologies Pty. Ltd.  
unit 4, 476 Gardeners Rd.  
Alexandria, New South Wales 2015, Australia

Drug Labeler Code: 068504

**C. Proprietary Name**

estroPLAN®

**D. Drug Product Established Name**

cloprostenol injection

**E. Pharmacological Category**

Prostaglandin

**F. Dosage Form**

Injectable solution

**G. Amount of Active Ingredient**

250 mcg cloprostenol/mL (equivalent to 263 mcg cloprostenol sodium/mL)

**H. How Supplied**

20 mL and 100 mL multidose vials

**I. Dispensing Status**

Prescription (Rx)

**J. Dosage Regimen**

For use with gonadorelin to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows.

Use in reproductive synchrony programs similar to the following:

- Administer the first gonadorelin injection by intramuscular injection on Day 0.
- Administer 2 mL of estroPLAN® by intramuscular injection 6 to 8 days after the first gonadorelin injection.
- Administer the second gonadorelin injection 30 to 72 hours after the estroPLAN® injection.

- Perform FTAI 8 to 24 hours after the second gonadorelin injection, or inseminate cows on detected estrus using standard herd practices.

**K. Route of Administration**

Intramuscular injection

**L. Species/Class**

Lactating dairy cows

**M. Indication**

For use with gonadorelin to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows.

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

Estrumate®; cloprostenol injection; NADA 113-645; Intervet, Inc.

**O. Effect of Supplement**

This supplement provides for the addition of the indication “For use with gonadorelin to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows.”

**II. BIOEQUIVALENCE**

CVM did not require additional bioequivalence information for this supplemental approval. The FOI Summary for the original approval of ANADA 200-310, dated May 13, 2004, contains a summary of the basis for granting a biowaiver for **estroPLAN®** (cloprostenol injection) for beef and dairy cows.

**III. HUMAN FOOD SAFETY**

CVM did not require human food safety studies for this supplemental approval.

**IV. USER SAFETY**

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

**USER SAFETY WARNINGS:**

Not for use in humans. Keep this and all drugs out of the reach of children.

**Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product.**

**estroPLAN®** is readily absorbed through the skin and can cause abortion and/or bronchospasms. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.

To obtain a copy of the Safety Data Sheet (SDS) or for technical assistance, contact Parnell at 1-800-88-PARNELL (1-800-887-2763).

**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 **estroPLAN<sup>®</sup>**, when used according to the label, is safe and effective for the for the effect of supplement in the General Information Section above.

Additionally, data demonstrate that residues in food products derived from lactating dairy cows treated with **estroPLAN<sup>®</sup>** will not represent a public health concern when the product is used according to the label.