**GONABREED- gonadorelin acetate injection, solution**
**Parnell Technologies Pty Ltd**

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**GONABREED**

Approved by FDA under ANADA # 200-541

**GONAbreed®**

(gonadorelin acetate)

Equivalent to 100 mcg gonadorelin/mL

Sterile solution

**For the treatment of cystic ovaries in dairy cattle**

**For use with cloprostenol sodium to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows and beef cows.**

**CAUTION:** Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

## DESCRIPTION:

GONAbreed is a sterile solution containing 100 micrograms of gonadorelin (GnRH) as gonadorelin acetate per milliliter suitable for intramuscular or intravenous administration according to the indication. Gonadorelin is a decapeptide composed of the sequence of amino acids –

5-oxoPro-His-Trp-Ser-Tyr-Gly-Leu-Arg-Pro-Gly-$NH_2$ –

a molecular weight of 1182.32 and empirical formula $C_{55}H_{75}N_{17}O_{13}$. The acetate salt has a molecular weight of 60.05 and an empirical formula $C_{55}H_{75}N_{17}O_{13}$. $C_2H_4O_2$.

Gonadorelin is the hypothalamic releasing factor responsible for the release of gonadotropins (e.g., LH, FSH) from the anterior pituitary. Synthetic gonadorelin is physiologically and chemically identical to the endogenous bovine hypothalamic releasing factor.

## PHARMACOLOGY AND TOXICOLOGY:

Endogenous gonadorelin is synthesized and/or released from the hypothalamus during various stages of the bovine estrous cycle following appropriate neurogenic stimuli. It passes via the hypophyseal portal vessels, to the anterior pituitary to effect the release of gonadotrophins (e.g. LH, FSH). Synthetic gonadorelin administered intravenously or intramuscularly also causes the release of endogenous LH or FSH from the anterior pituitary.

Gonadorelin acetate has been shown to be safe. The $LD_{50}$ for mice and rats is greater than 60 mg/kg, and for dogs, greater than 600 mcg/kg, respectively. No untoward effects were noted among rats or dogs administered 120 mcg/kg/day or 72 mcg/kg/day intravenously for 15 days.

It has no adverse effects on heart rate, blood pressure, or EKG to unanesthetized dogs at 60 mcg/kg. In anesthetized dogs it did not produce depression of myocardial or system hemodynamics or adversely affect coronary oxygen supply or myocardial oxygen requirements.

The intravenous administration of 60 mcg/kg/day of gonadorelin acetate to pregnant rats and rabbits during organogenesis did not cause embryotoxic or teratogenic effects.

The intramuscular administration of 1,000 mcg to normally cycling dairy cattle had no effect on hematology or blood chemistry.

Further, gonadorelin acetate does not cause irritation at the site of intramuscular administration in dogs. The dosage administered was 72 mcg/kg/day for seven (7) days.

## INDICATIONS AND DOSAGE:

### Cystic Ovaries

GONAbreed is indicated for the treatment of ovarian follicular cysts in dairy cattle. Ovarian cysts are non-ovulated follicles with incomplete luteinization which result in nymphomania or irregular estrus.

Historically, cystic ovaries have responded to an exogenous source of luteinizing hormone (LH) such as human chorionic gonadotrophin. GONAbreed initiates release of endogenous LH to cause ovulation and luteinization.

The recommended intravenous or intramuscular dosage of GONAbreed is 100 mcg (1 mL) per cow.

### Reproductive Synchrony

GONAbreed is indicated for use with cloprostenol sodium to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows and beef cows.

The recommended intramuscular dosage of GONAbreed is 100 mcg (1 mL) per cow, used in reproductive synchrony programs similar to the following:

Administer the first GONAbreed injection (1 mL) at Time 0.

Administer 500 mcg cloprostenol (as cloprostenol sodium) by intramuscular injection 6 to 8 days after the first GONAbreed injection.

Administer the second GONAbreed injection (1 mL) 30 to 72 hours after the cloprostenol sodium injection.

Perform FTAI 0 to 24 hours after the second GONAbreed injection, or inseminate cows on detected estrus using standard herd practices.

## TARGET ANIMAL SAFETY:

In addition to the target animal safety information presented in the section addressing pharmacology and toxicology, target animal safety of, and injection site reactions to, GONAbreed when used with cloprostenol sodium were evaluated during the conduct of the effectiveness field studies. The incidence of health abnormalities was not significantly greater in cows administered GONAbreed than cows administered a placebo injection.

## EFFECTIVENESS:

The effectiveness of GONAbreed (gonadorelin acetate) for use with cloprostenol sodium to synchronize estrous cycles to allow for FTAI in lactating dairy cows was demonstrated in a field study at 10 different locations in the U.S. Four of the locations represented conditions that would typically cause heat stress in lactating cows. A total of 1607 healthy, non-pregnant, primiparous or multiparous lactating dairy cows within 40-150 days postpartum were enrolled in the study. A total of 805 cows were administered GONAbreed (1 mL; 100 mcg gonadorelin as the acetate salt) and 802 cows were administered an equivalent volume of water for injection as an intramuscular injection twice in the following regimen:

Day 0: 1 mL GONAbreed or sterile water for injection

Day 7: 500 mcg cloprostenol (as cloprostenol sodium)

Day 9: 1 mL GONAbreed or sterile water for injection

Fixed time AI was performed on Day 10, approximately 11 - 31 hours after the Day 9 injection. Cows were evaluated for pregnancy on Day 45 ± 5 days by trans-rectal ultrasound or rectal palpation. Pregnancy rate to FTAI was significantly higher ($P < 0.0001$) in cows treated with GONAbreed (33.4%) than the pregnancy rate to FTAI in cows treated with water (13.6%). The environmental

condition (heat stress or not heat stress) did not affect the conclusion of effectiveness.

The effectiveness of GONAbreed (gonadorelin acetate) for use with cloprostenol sodium to synchronize estrous cycles to allow for FTAI in beef cows was demonstrated in a field study at 10 different locations in the U.S. A total of 706 healthy, non-pregnant, primiparous or multiparous beef cows within 40-150 days postpartum were enrolled in the study. A total of 364 cows were administered GONAbreed (1 mL; 100 mcg gonadorelin as the acetate salt) and 342 cows were administered an equivalent volume of water for injection as an intramuscular injection twice in the following regimen:

Day 0: 1 mL GONAbreed or sterile water for injection

Day 7: 500 mcg cloprostenol (as cloprostenol sodium)

Day 9: 1 mL GONAbreed or sterile water for injection

Fixed time AI was performed immediately after the Day 9 injection. Cows were evaluated for pregnancy on Day 55 ± 5 days by trans-rectal ultrasound. Pregnancy rate to FTAI was significantly higher (P = 0.0006) in cows treated with GONAbreed (21.7%) than the pregnancy rate to FTAI in cows treated with water (7.4%).

Each mL of GONAbreed contains:

Gonadorelin (as gonadorelin acetate) 100 mcg

Benzyl alcohol 10 mg

Sodium chloride 7.47 mg

Sodium phosphate monobasic 8.3 mg

Sodium phosphate dibasic 4.8 mg

Water for injection, USP, q.s.

pH adjusted with hydrochloric acid or sodium hydroxide.

**PRECAUTIONS:**

**Not for use in humans.**

**Keep this and all drugs out of reach of children.**

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To obtain an MSDS or for technical assistance, contact Parnell at 1-800-88-PARNELL (1-800-887-2763). To report suspected adverse drug experiences, contact Parnell at 1-800-88-PARNELL (1-800-887-2763). For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS, or http://www.fda.gov/reportanimalae.

Discard remaining product 180 days after first use. Once broached, product may be stored at temperatures up to 25°C (77°F).

**KEEP UNOPENED VIALS REFRIGERATED: 2° - 8°C (36° - 46°F).**

**HOW SUPPLIED:**

GONAbreed is available in a concentration of 100 mcg gonadorelin/mL as gonadorelin acetate.

GONAbreed is supplied in multidose vials containing 20 mL and 100 mL of sterile solution.

Manufactured by:

**PARNELL TECHNOLOGIES PTY. LTD.**

4/476 Gardeners Road

Alexandria NSW 2015 Australia

Owner of the trademark GONAbreed

Distributed by:

**PARNELL U.S. 1, Inc**

7015 College Boulevard

Level 6

Overland Park, KS 66211

Approved by FDA under ANADA # 200-541

20mL: 50297b-07-August 20
100mL: 50303b-05-August 20

**PRINCIPAL DISPLAY PANEL - 20 mL Bottle**

**GONAbreed®**

**(gonadorelin acetate)**

Equivalent to 100 mcg gonadorelin/mL

Sterile solution

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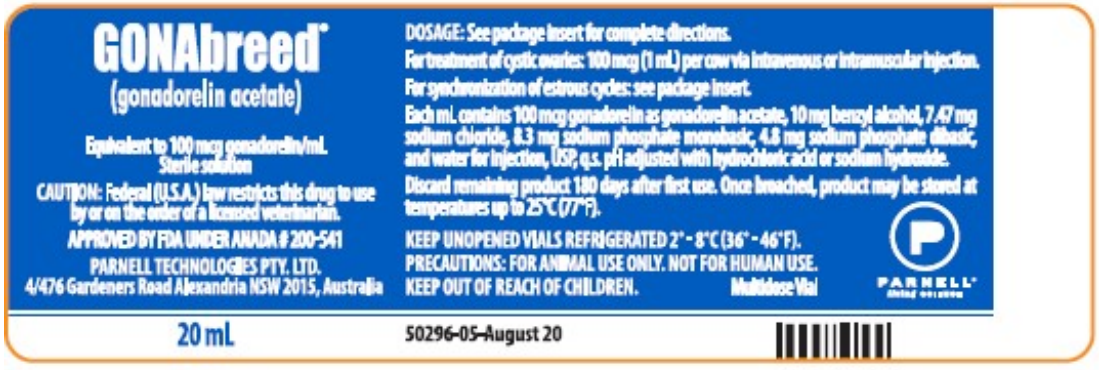
**PARNELL TECHNOLOGIES PTY. LTD.**

**4/476 Gardeners Road Alexandria NSW 2015 Australia**

20 mL




**PRINCIPAL DISPLAY PANEL - 20 mL Carton**

**GONAbreed**

(gonadorelin acetate)

Equivalent to 100 mcg gonadorelin/mL

Sterile solution

**FOR ANIMAL USE ONLY**

**NOT FOR HUMAN USE**

**KEEP OUT OF REACH OF CHILDREN**

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20 mL


**PRINCIPAL DISPLAY PANEL - 100 mL Bottle**

**GONAbreed®**

**(gonadorelin acetate)**

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**PARNELL TECHNOLOGIES PTY. LTD.**

**4/476 Gardeners Road Alexandria NSW 2015 Australia**

100 mL


**PRINCIPAL DISPLAY PANEL - 100 mL Carton**

**GONAbreed®**

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100 mL


# GONABREED

gonadorelin acetate injection, solution

| Product Information | | | |
|---|---|---|---|
| **Product Type** | PRESCRIPTION ANIMAL DRUG | **Item Code (Source)** | NDC:68504-002 |
| **Route of Administration** | INTRAMUSCULAR, INTRAVENOUS | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **GONADORELIN ACETATE** (UNII: 2RG1XQ1NYJ) (GONADORELIN - UNII:9O7312W37G) | GONADORELIN | 100 ug in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **BENZYL ALCOHOL** (UNII: LKG8494WBH) | 10 mg in 1 mL |
| **SODIUM CHLORIDE** (UNII: 451W47IQ8X) | 7.47 mg in 1 mL |
| **SODIUM PHOSPHATE, MONOBASIC** (UNII: 3980JIH2SW) | 8.3 mg in 1 mL |
| **SODIUM PHOSPHATE, DIBASIC** (UNII: GR686LBA74) | 4.8 mg in 1 mL |
| **HYDROCHLORIC ACID** (UNII: QTT17582CB) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |

| | |
|---|---|
| **water** (UNII: 059QF0KO0R) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:68504-002-01 | 1 in 1 CARTON | | |
| **1** | | 20 mL in 1 VIAL, MULTI-DOSE | | |
| **2** | NDC:68504-002-02 | 1 in 1 CARTON | | |
| **2** | | 100 mL in 1 VIAL, MULTI-DOSE | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANADA | ANADA200541 | 03/01/2013 | |

## Labeler - Parnell Technologies Pty Ltd (742511504)

## Registrant - Parnell Technologies Pty Ltd (742511504)

Revised: 2/2021 Parnell Technologies Pty Ltd