BioRelease® Deslorelin (BRD) is a suspension of synthetic GnRH analogue Deslorelin in a unique BioRelease® vehicle for the induction of ovulation in mares.

~ Each mL contains 1.25 mg Deslorelin (as Deslorelin acetate) ~

**Description**
Ready-to-inject suspension containing Deslorelin acetate 1.25 mg/mL. Presented as individual sterile amber glass vials containing 10 mL and packaged inouters of 10 for handling. Each vial provides 10 x 1 mL doses.

**Actions**
The long duration of oestrus in mares, and the varying time from the onset of oestrus to ovulation, typically results in the need for multiple breedings or inseminations in order to achieve conception. BioRelease Deslorelin (BRD) assists ovulation within 48 hours after treatment in oestrous mares with a developing follicle greater than 30 mm in diameter. Deslorelin induces ovulation by increasing the levels of endogenous luteinizing hormone.

BioRelease Deslorelin (BRD) is intended to optimise breeding management by shortening the oestrous period, thereby enabling more efficient stallion management. Abnormalities in neonatal viability and foal behaviour related to the use of deslorelin have not been observed in foals born to treated mares.

**Indications**
BioRelease Deslorelin (BRD) is indicated for inducing ovulation within 48 hours in oestrous mares with an ovarian follicle greater than 30 mm in diameter.

**Dosage and Administration**
Dose Rate: 1.0 mL (1.25 mg Deslorelin) by intramuscular injection to oestrus mares once an ovarian follicle greater than 30 mm in diameter has been demonstrated by rectal palpation and/or ultrasonography.

Do not store BioRelease Deslorelin (BRD) in plastic syringes. Shake vial well and draw up suspension only as ready to administer.

**Example management of frozen semen insemination as reported by veterinarians in practice:**
Once a follicle greater than 35 mm has been detected 1 mL BioRelease Deslorelin (BRD) is administered IM at 8 pm (Day 0). Mare is re-scanned 36 hours later (8 am on Day 2) and regularly thereafter to determine the time of ovulation. Insemination is performed as determined by the veterinarian. The majority of mares are expected to ovulate between 12 pm and 4 pm on Day 2 [i.e. 40 - 44 hours post-BRD injection].

**Withholding Period**
Meat: Zero (0) days

**Storage**
Store at room temperature (below 30°C). Store vials in an upright position. Protect from light. Do not freeze.

The APVMA registered shelf-life is 48 months (4 years) from date of manufacture.

**Availability**
S4 - For supply by veterinary prescription (APVMA Registration Number 64329).

NOTE: Please refer to product leaflet prior to use.
**BioRelease® Deslorelin**

**GnRH analogue Deslorelin in a BioRelease® vehicle for Induction of Ovulation in Mares**

- Fully registered in Australia and New Zealand
- Demonstrated efficacy in Australian field use [Studies show ovulation within 48 hrs in 93.8% and 95.9% of mares and no extension of inter-ovulatory interval]
- Formulated in a BioRelease® vehicle for prolonged-release of the active ingredient Deslorelin acetate 1.25 mg/mL
- Ready-to-inject suspension with a 4 year unrefrigerated shelf-life
- Each 10 mL multidose vial provides 10 x 1 mL intramuscular doses

**Ovulation within 48 Hours of Treatment**

<table>
<thead>
<tr>
<th></th>
<th>BioRelease® Deslorelin</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>93.8% (30/32)</td>
<td>21.9% (7/32)</td>
</tr>
<tr>
<td>(27/31)</td>
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**More details of Australian studies overleaf.**

APVMA Registration No. 64329 (Australia), ACVM Registration No. A10295 (New Zealand).

**Manufactured by**

BioRelease Technologies Australasia manufactures BioRelease® Deslorelin (BRD) for the Australian and New Zealand markets.

“BioRelease®” refers to a group of proprietary drug delivery formulations that enable delivery of various drugs in a precise release profile following intramuscular injection.

These biocompatible formulations are produced specifically for each drug based on its chemistry and desired release profile and work for a variety of drug classes including steroids, peptides, anthelmintics, D2-receptor antagonists and antibiotics.

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**Caledonian Holdings Veterinary Pharmaceuticals**

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PRODUCT INFORMATION

BioRelease® Deslorelin (BRD) is a suspension of the synthetic GnRH analogue Deslorelin in a unique BioRelease® vehicle providing prolonged-release of the active ingredient to induce ovulation in mares.

Presentation: Sterile amber glass vial containing 10 mL Deslorelin 1.25 mg/mL (as deslorelin acetate) in a ready-to-inject suspension.

Indications: BioRelease Deslorelin (BRD) is indicated for inducing ovulation within 48 hours in oestrus mares with an ovarian follicle greater than 30 mm in diameter. Follicular size should be determined by rectal palpation and/or ultrasonography prior to treatment.

Actions: Natural GnRH is produced in the hypothalamus and has a short half-life of 5 - 10 minutes. Deslorelin induces ovulation by increasing the levels of endogenous luteinizing hormone. BioRelease Des lorelin (BRD) is a decapeptide and does not cause antibody formation so may be used repeatedly without a reduction in efficacy. No down-regulation has been demonstrated following BioRelease Deslorelin (BRD) use. Follicular suppression does not occur and inter-ovulatory interval is not extended.

Dosage: 1.0 mL (1.25 mg Deslorelin) by intramuscular injection once an ovarian follicle greater than 30 mm diameter has been detected.

Storage: 4 year shelf-life at room temperature (below 30°C). Do not store in plastic syringes. Shake vial well and draw up only as ready to inject.

SUMMARY OF 2013 COMPARATIVE EFFICACY STUDY *

Investigators: Dr Angus McKinnon BVSc, MSc, Dip ACT and ABVP and Dr Sean Finan MVSc at Goulburn Valley Equine Hospital, Australia.

Study Outline: In the trial, oestrus was induced by PGF2α administered to mares with a corpus luteum and a maximum follicle size of <25 mm on ultrasonography. Mares were examined until detection of clinical signs of oestrus, a dominant follicle of >30 mm diameter and uterine oedema pattern of 3 (McKinnon et al 1987). Mares were randomly assigned to groups and given intramuscularly either 1 mL compound sodium lactate solution (Baxter Healthcare Pty) [32 cycles, Group A], 1.25 mg of BioRelease Deslorelin (BioRelease® Deslorelin (BRD) - Caledonian Holdings) [32 cycles, Group B] or an implant of 2.1 mg deslorelin (Ovuplant® - Peptech Animal Health Australia) [31 cycles, Group C]. Once treated the mares were examined by rectal palpation and ultrasonography every 12 hours until ovulation was diagnosed. All treatments were administered in the neck of the mares, Ovuplant implants were not removed and all injection sites were examined regularly to assess any reaction at the site.

Results:

There was a significant difference (p<0.05) in the proportion of mares that ovulated within 48 hrs of treatment between groups A (21.9% [7/32]) and groups B and C (93.8% [30/32] and 87.1% [27/31] respectively) but groups B and C did not differ significantly. A significant difference (p<0.05) was found in the number of injection site reactions between treatment groups with group C (64.5% [20/31]) having a higher incidence than groups A (0% [0/32]) or B (15.6% [5/32]). A generalised linear regression showed that the median time taken for injection site reactions to regress was greater in mares treated with Ovuplant (Group C) taking 72 hours compared with 36 hours for group B.

Conclusion: This work shows that BioRelease Deslorelin (BRD) is at least as effective as Ovuplant for the induction of ovulation in oestrus mares with a dominant follicle of greater than 30 mm in diameter, and results in fewer injection site reactions.

SUMMARY OF 2012 RETROSPECTIVE STUDY OF USE IN AUSTRALIA *

Investigators: Dr Cameron Collins BVSc, MACVSc, MRCVS, GAICD (Scone Equine Hospital), Dr Angus McKinnon BVSc, MSc, Dip ACT and ABVP (Goulburn Valley Equine Hospital) and Dr Edwina Lamkin BSc, BVMS (Caledonian Holdings).

Study Outline: The objective was to assess the efficacy and safety of 1 mL BioRelease Deslorelin (BRD) in actual clinical use on Thoroughbred studs in two major equine reproductive regions of Australia. This retrospective case study involved collection of data from mares managed at two Thoroughbred Studs under typical Australian conditions from August to December 2011. Reproductive record sheets for 265 mares were retrieved and a total of 269 oestrus cycles were suitable for inclusion in the study.

Results:

There was no significant difference (p=0.149) in the proportion of mares that ovulated within 48 hrs of treatment with BioRelease Des lorelin (BRD) and Ovuplant (95.9% [166/173] and 90.2% [46/51] respectively). The mean inter-ovulatory interval of ≤20.86 days for mares in this study treated with BioRelease Deslorelin (BRD) [n=50] is normal, as established to be 20.6 days by Hughes 1975*. The mean inter-ovulatory interval of ≤20.86 days for 1 mL BioRelease Deslorelin (BRD) in this study is lower than that reported for Ovuplant by Farquar 2000* and Johnson 2002* as 25.8 days and 25.4 days respectively.

Conclusion: This study demonstrates, in actual Australian field use, equivalence in the efficacy of 1 mL BioRelease Deslorelin (BRD) and Ovuplant in the induction of ovulation within 48 hours of treatment once a follicle ≥30 mm has been detected. An important finding is the normal inter-ovulatory interval after BioRelease Deslorelin (BRD) treatment which is lower than that for Ovuplant in this study and much lower than that established for Ovuplant in a number of independent studies.

*Further product and study info available on request. *Unpublished data.