

**Product name:** Ovurelin (A009949)  
**Revision date:** 9 Nov 2023

**Page:** 1 of 12  
**Country:** New Zealand

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**100 mL Container – Label**

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**WARNING**  
**KEEP OUT OF REACH OF CHILDREN**  
**FOR ANIMAL TREATMENT ONLY**  
**RESTRICTED VETERINARY MEDICINE**

**Ovurelin**

**ACTIVE CONSTITUENT**

Each mL contains 100 µg GONADORELIN (as acetate).

For use in the synchronisation of oestrus, treatment of anoestrus and cystic ovaries in cattle.

**100 mL**

**DIRECTIONS FOR USE**

**Read package insert prior to use.**

Intramuscular injection into the anterior half of the neck.

**DOSE RATE**

Oestrus synchronisation	See package insert
Prevention of delayed ovulation	2.5 mL
Improvement of postpartum fertility	2.5 mL
Cystic ovaries	5 mL

**WITHHOLDING PERIODS**

Milk and meat: **NIL**

**STORAGE**

Store below 25 °C (room temperature). Protect from light. Discard all open vials 28 days after broaching.

Registered pursuant to the ACVM Act 1997, No. A009949  
See [www.foodsafety.govt.nz](http://www.foodsafety.govt.nz) for registration conditions.

Elanco New Zealand  
106 Wiri Station Road, Manukau, Auckland 2104  
Customer Info Line: 0800 446 121

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BATCH:  
EXPIRY:



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***CARTON – Front Panel 100 mL***

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**WARNING**  
**KEEP OUT OF REACH OF CHILDREN**  
**FOR ANIMAL TREATMENT ONLY**  
**RESTRICTED VETERINARY MEDICINE**

**Ovurelin**  
**Gonadorelin Acetate Injection**

**ACTIVE CONSTITUENT**

Each mL contains 100 µg GONADORELIN (as acetate).

For use in the synchronisation of oestrus, treatment of anoestrus and cystic ovaries in cattle. For use with Prosynch and oestrus synchrony programmes.

Pictogram of cow

Elanco [logo]

**100 mL**

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***CARTON – Back and side Panel 100 mL***

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**INDICATIONS**

For use in oestrus synchronisation programmes in combination with PGF2α, treatment of anoestrus, prevention of delayed ovulation, improvement of postpartum fertility, and the treatment of cystic ovaries in cattle.

**DIRECTIONS FOR USE**

**Read package insert prior to use.**

By intramuscular injection into the anterior half of the neck.

**DOSE RATE**

Oestrus synchronisation

Day 0: 1 mL GnRH

Day 7: 2 mL PGF2α

Day 9: 1 mL GnRH

Insemination 8 – 24 hours after 2<sup>nd</sup> gonadorelin acetate injection (GnRH)

Prevention of delayed ovulation      2.5 mL (250 µg gonadorelin)

Improvement of postpartum fertility      2.5 mL (250 µg gonadorelin)

Cystic ovaries      5 mL (500 µg gonadorelin)



A handwritten signature in blue ink, likely of a representative from Elanco Australasia Pty Ltd.

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### WITHHOLDING PERIODS

Milk and meat: **NIL**

### STORAGE

Store below 25 °C (room temperature). Protect from light.  
Discard all open vials 28 days after broaching.

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Barcode

### READ ENTIRE LABEL BEFORE USE

May cause an allergic skin reaction.



### HANDLING PRECAUTIONS

Wear protective gloves. Avoid breathing vapour. Contaminated work clothing should not be allowed out of the workplace.

### FIRST AID

Take off contaminated clothing and wash it before reuse. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice or attention. For advice contact the National Poisons Centre 0800 POISON (0800 764 766).

### DISPOSAL

Preferably dispose of the product by use. Otherwise dispose of product and packaging in an approved landfill or other approved facility.

EPA statements

**CARTON – Side Panel - 100 mL**

**Ovurelin**  
**Gonadorelin Acetate Injection**

**CARTON – End panel (top) 100 mL**

**Ovurelin**  
**Gonadorelin Acetate Injection**

**100 mL**

**CARTON – End flap 100 mL**

BATCH:  
EXPIRY:



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### 20 mL Container – Label

For use in the synchronisation of oestrus, treatment of anoestrus and cystic ovaries in cattle.  
Read package insert prior to use.

#### WITHHOLDING PERIODS

Milk and meat: **NIL**

**WARNING**  
**KEEP OUT OF REACH OF CHILDREN**  
**FOR ANIMAL TREATMENT ONLY**  
**RESTRICTED VETERINARY MEDICINE**

**Ovurelin**  
Gonadorelin Acetate Injection  
**ACTIVE CONSTITUENT**  
Each mL contains  
**100 µg GONADORELIN (as acetate).**

*Elanco logo*

**20 mL**

**STORAGE:** Store below 25 °C (room temperature).  
Protect from light. Discard all open vials 28 days after broaching.

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***CARTON – Front and Back Panels 20 mL***

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**WARNING**  
**KEEP OUT OF REACH OF CHILDREN**  
**FOR ANIMAL TREATMENT ONLY**  
**RESTRICTED VETERINARY MEDICINE**

**Ovurelin**

**Gonadorelin Acetate Injection**

**ACTIVE CONSTITUENT**

Each mL contains 100 µg GONADORELIN (as acetate).

For use in the synchronisation of oestrus, treatment of anoestrus and cystic ovaries in cattle.

For use with Prosynch and oestrus synchrony programmes.

***Elanco [logo]***

Pictogram of cow

**20 mL**

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***CARTON – Side Panels (20 mL)***

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**DIRECTIONS FOR USE**

**Read package insert prior to use.**

By intramuscular injection into the anterior half of the neck.

**DOSE RATE**

Oestrus synchronisation

Day 0: 1 mL GnRH

Day 7: 2 mL PGF2α

Day 9: 1 mL GnRH

Insemination 8 – 24 hours after 2<sup>nd</sup> gonadorelin acetate injection (GnRH)

Prevention of delayed ovulation      2.5 mL (250 µg gonadorelin)

Improvement of postpartum fertility      2.5 mL (250 µg gonadorelin)

Cystic ovaries      5 mL (500 µg gonadorelin)

**WITHHOLDING PERIODS**

Milk and meat: **NIL**

**STORAGE**

Store below 25 °C (room temperature). Protect from light.

Discard all open vials 28 days after broaching.



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**READ ENTIRE LABEL BEFORE USE**

May cause an allergic skin reaction.



**HANDLING PRECAUTIONS**

Wear protective gloves. Avoid breathing vapour. Contaminated work clothing should not be allowed out of the workplace.

**FIRST AID**

Take off contaminated clothing and wash it before reuse. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice or attention. For advice contact the National Poisons Centre 0800 POISON (0800 764 766).

**DISPOSAL**

Preferably dispose of the product by use. Otherwise dispose of product and packaging in an approved landfill or other approved facility.

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[Barcode]

**CARTON – End flap (20 mL)**

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**EXPIRY:**



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**LEAFLET – 100 mL and 20 mL**

**WARNING**  
**KEEP OUT OF REACH OF CHILDREN**  
**FOR ANIMAL TREATMENT ONLY**  
**RESTRICTED VETERINARY MEDICINE**

Elanco [logo]

**Ovurelin**

**Gonadotropin Releasing Hormone (GnRH) Sterile Injection**

**ACTIVE CONSTITUENT:** Each mL contains 100 µg GONADORELIN (as acetate).

**DESCRIPTION**

Ovurelin is a clear, colourless, sterile solution containing 100 µg/mL gonadorelin (as acetate) for use in the synchronisation of oestrus in combination with PGF2α, treatment of anoestrus, prevention of delayed ovulation and improvement of postpartum fertility and the treatment of cystic ovaries, in cattle.

**MODE OF ACTION**

Ovurelin contains gonadorelin, a decapeptide identical to the endogenous Gonadotropin Releasing Hormone (GnRH), which controls the production and secretion of Luteinizing Hormone (LH) and Follicle Stimulating Hormone (FSH) by the pituitary gland. Both LH and FSH have a direct effect on the ovary: FSH stimulates follicle development, while LH induces ovulation and luteinization.

Injection of Ovurelin induces the simultaneous release of FSH and LH thereby stimulating the maturation of ovarian follicles, ovulation and development of the corpus luteum.

**INDICATIONS**

1. *Oestrus synchronisation*

Oestrus synchronisation is a procedure developed to synchronise ovulation for timed breeding. Procedures involving a combination of PGF2α/GnRH have been found to be superior in terms of pregnancy rate and calving to conception intervals in dairy cattle. Using a combination of PGF2α/GnRH also results in a more precise synchronisation hence allowing fixed-time insemination. Fixed-time insemination in turn allows insemination of large groups of cows together, without the need for oestrus detection.

The PGF2α/GnRH procedure for dairy cattle reproductive management is as follows:

- (i) Day 0 – GnRH administration:  
GnRH induces ovulation and luteinisation of dominant follicles present at the time of treatment and causes the smaller follicles to undergo atresia. A new follicular wave is subsequently recruited and a new dominant follicle gradually emerges.
- (ii) Day 7 – PGF2α administration:



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7 days after the first treatment with GnRH, PGF2 $\alpha$  is administered. Administration of PGF2 $\alpha$  causes luteolysis of the GnRH induced corpus luteum. The new dominant follicle is ready to ovulate 2 – 3 days later.

(iii) Day 9 – GnRH administration:

The second GnRH dose induces an LH surge, which further synchronises the dominant follicle, resulting in ovulation of predictable timing, allowing fixed time insemination 8 – 24 hours later.

(iv) Insemination 8 – 24 hours after the second GnRH, regardless of the presence or absence of visible oestrus.

2. *Treatment of Anoestrus*

- (i) Day 0: GnRH administration and insertion of P4 device.
- (ii) Day 7: PGF2 $\alpha$  administration.
- (iii) Day 7 – 9: AI to detected oestrus during next 72 hours.
- (iv) Day 10: GnRH administration and fixed-time AI of all non-bred cows during the next 24 hours.

3. *Prevention of delayed ovulation*

Delayed ovulation can result in the reduction of the rate of conception due to asynchrony between ova and sperm at the time of artificial insemination (AI). Delayed ovulation can be prevented by the administration of Ovurelin, which stimulates the release of LH and hence induces ovulation.

4. *Improvement of postpartum fertility*

It is important that normal ovarian cyclical activity resumes in the early post-partum period to minimise the calving to conception interval or 'days open'. Ovurelin given in the first 40 days of the postpartum period may initiate the ovarian cyclical activity to resume, and reduce the incidence of postpartum infertility in cows.

5. *Treatment of cystic ovaries*

Cystic ovaries are an infertility problem in dairy cattle, which may be of single or multiple and of follicular or luteal origin. Clinical signs of ovarian cysts include irregular oestrus cycles, anoestrus and nymphomania. Ovarian cysts can be diagnosed by rectal palpation of the structures on one or both ovaries. Treatment of cystic ovaries with Ovurelin may result in the recommencement of normal cyclical activity, through the response of ovarian cysts to the released LH induced by Ovurelin. Ovurelin given in the first 40 days of the postpartum period may initiate the ovarian cyclical activity to resume, and reduce the incidence of postpartum infertility in cows.





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## **DIRECTIONS FOR USE**

For intramuscular injection to the anterior half of the neck.

### ***Dose rate***

#### ***Oestrus synchronisation:***

Day 0	1 mL Ovurelin (100 µg gonadorelin)
Day 7	2 mL Ovuprost (500 µg cloprostenol)
Day 9	1 mL Ovurelin (100 µg gonadorelin)
Insemination 8 – 24 hours after 2 <sup>nd</sup> injection of Ovurelin	

#### ***Treatment of anoestrus***

##### Prosynch (Hybrid) Programme

Day 1	1 mL Ovurelin (+P4)
Day 7	2 mL Ovuprost (remove P4)
Day 7 – 9	Mate to detected oestrus
Day 10	1 mL Ovurelin to unmated cows
FTAI within 24 hours of 2 <sup>nd</sup> Ovurelin injection	

##### Prosynch (FTAI) Programme

Day 1	1 mL Ovurelin (+P4)
Day 7	2 mL Ovuprost (remove P4)
Day 9	1 mL Ovurelin
FTAI between 16 – 20 hours after 2 <sup>nd</sup> Ovurelin injection	

#### ***Prevention of delayed ovulation:***

2.5 mL Ovurelin (250 µg gonadorelin)

#### ***Improvement of postpartum fertility:***

2.5 mL Ovurelin (250 µg gonadorelin)

#### ***Cystic ovaries:***

5 mL Ovurelin (500 µg gonadorelin)

## **ADDITIONAL SAFETY STATEMENTS**

- Care should be taken to avoid accidental self-injection and needle stick injury when administering this product.
- In the event of accidental self-injection, seek medical advice immediately.
- Not to be administered by pregnant women.
- Avoid contact with the eyes and skin.
- Wash hands after use.
- If poisoning occurs, contact a doctor immediately or call the National Poisons Centre for advice (0800 764 766).

## **WITHHOLDING PERIODS**

Milk and Meat: **NIL**



A handwritten signature in blue ink, likely of a regulatory official, written over the bottom right of the stamp.

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## STORAGE

Store below 25 °C (room temperature). Protect from light. Use within 28 days of broaching the vial or flexipack when used in a sterile manner or discard the unused portion.

## READ ENTIRE LABEL BEFORE USE

### WARNING

May cause an allergic skin reaction.



### HANDLING PRECAUTIONS

Wear protective gloves. Avoid breathing vapour. Contaminated work clothing should not be allowed out of the workplace.

### FIRST AID

Take off contaminated clothing and wash it before reuse. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice or attention. For advice contact the National Poisons Centre 0800 POISON (0800 764 766).

### EMERGENCY RESPONSE

Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. For specialist advice in an emergency call CHEMTREC 0800 425 459. If additional hazard information is required, refer to the Safety Data Sheet. For a copy please go to [www.elanco.co.nz](http://www.elanco.co.nz).

### DISPOSAL

Preferably dispose of the product by use. Otherwise dispose of product and packaging in an approved landfill or other approved facility.

## PRESENTATION

20 mL and 100 mL.

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Elanco New Zealand  
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**Outer (shipper) – 100 mL**

**WARNING**  
**KEEP OUT OF REACH OF CHILDREN**  
**FOR ANIMAL TREATMENT ONLY**  
**RESTRICTED VETERINARY MEDICINE**

**WARNING**

May cause an allergic skin  
reaction



**Ovurelin**

**ACTIVE CONSTITUENT**

Each mL contains 100 µg GONADORELIN (as acetate).

**For use in the synchronisation of oestrus, treatment of anoestrus and cystic ovaries in cattle. For use with Prosynch and oestrus synchrony programmes.**

**STORAGE**

Store below 25 °C (room temperature). Protect from light.

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**16 x 100 mL**

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BATCH:  
EXPIRY:

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**Outer (shipper) – 20 mL**

**WARNING**  
**KEEP OUT OF REACH OF CHILDREN**  
**FOR ANIMAL TREATMENT ONLY**  
**RESTRICTED VETERINARY MEDICINE**

**Ovurelin**  
**Gonadorelin Acetate Injection**

[Barcode]

**ACTIVE CONSTITUENT:** Each mL contains  
**100 µg GONADORELIN (as acetate).**

**For use in the synchronisation of oestrus,**  
**treatment of anoestrus and cystic ovaries**  
**in cattle. For use with Prosynch and**  
**oestrus synchrony programmes.**

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**108 x 20 mL**

**WARNING**  
May cause an allergic skin reaction



**STORAGE**  
Store below 25 °C (room temperature). Protect from light.

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**BATCH:**  
**EXPIRY:**