B. PACKAGE LEAFLET

PACKAGE LEAFLET
RELOSYL 50 micrograms/ml solution for injection for cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Laboratorios SYVA S.A.
Calle Marqués de la Ensenada, 16
28004 Madrid
Spain

Manufacturer responsible for batch release:
Laboratorios SYVA S.A.
Avenida del Párroco Pablo Díez, 49-57
San Andrés del Rabanedo
24010 León
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

RELOSYL 50 micrograms/ml solution for injection for cattle.
Gonadorelin (as acetate)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:
Gonadorelin (as gonadorelin acetate) 50 µg

Excipients:
Benzyl alcohol (E1519) 9 mg

Clear, colourless or almost colourless solution free from visible particles.

4. INDICATION(S)

In cattle (cows and heifers):
Treatment of ovarian follicular cysts.
In association with artificial insemination to optimise the time of ovulation.

Induction and synchronisation of oestrus and ovulation in combination with prostaglandin $F_{2\alpha}$ ($PGF_{2\alpha}$) with or without progesterone as part of Fixed Time Artificial Insemination (FTAI) protocols:
-In cycling cows: To be used in combination with $PGF_{2\alpha}$ or analogue.
-In cycling and non-cycling cows and heifers: To be used in combination with $PGF_{2\alpha}$ or analogue and progesterone releasing device.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to gonadorelin or to any of the excipients.

6. ADVERSE REACTIONS

None.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle: cows and heifers.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intramuscular use.

- **Treatment of ovarian follicular cysts:** 100-150 micrograms of gonadorelin (as acetate) per animal (i.e. 2- 3 ml of the product per animal). If necessary, treatment can be repeated at intervals of 1-2 weeks.

- **In association with artificial insemination to optimise the time of ovulation**, improving the chances that the treated cow will become fertile: 100 micrograms of gonadorelin (as acetate) per animal (i.e. 2 ml of the product per animal). It must be administered at the same time as artificial insemination and/or 12 days after this.

The following timing of injection and insemination should be followed:
- Injection should be performed between 4 and 10 hours after oestrus detection.
- An interval of at least 2 hours between the injection of GnRH and artificial insemination is recommended.
- Artificial insemination should be carried out in accordance with the usual field recommendations, i.e., 12 to 24 hours after oestrus detection.

- **Induction and synchronisation of oestrus and ovulation in combination with prostaglandin $F_{2\alpha}$ ($PGF_{2\alpha}$) with or without progesterone as part of Fixed Time Artificial Insemination (FTAI) protocols:**

The following FTAI protocols have been commonly reported in the literature:

<u>In cycling cows:</u>

- Day 0 Inject 100 micrograms of gonadorelin (as acetate) per animal (2 ml of the product)
- Day 7 Inject PGF2α or analogue (luteolytic dose)
- Day 9 Inject 100 micrograms of gonadorelin (as acetate) per animal (2 ml of the product)
- Artificial insemination 16–20 hours later, or at observed oestrus if sooner.

Alternatively:

- Day 0 Inject 100 micrograms of gonadorelin (as acetate) per animal (2 ml of the product)
- Day 7 Inject PGF2α or analogue (luteolytic dose)
- Artificial insemination and injection of 100 micrograms of gonadorelin (as acetate) per animal (2 ml of the product) 60–72 hours later, or at observed oestrus if sooner.

<u>In cycling and non-cycling cows and heifers:</u>

- Insert intravaginal progesterone releasing device for 7-8 days.
- Inject 100 micrograms of gonadorelin (as acetate) per animal (2 ml of the product) at progesterone device insertion.
- Inject a luteolytic dose of PGF2α or analogue 24 hours prior to device removal.
- FTAI 56 hours after removal of the device, or
- Inject 100 micrograms of gonadorelin (as acetate) per animal (2 ml of the product) 36 hours after progesterone releasing device removal and FTAI 16 to 20 hours later.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIODS

Meat and offal: zero days.

Milk: zero hours.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 ºC.
Keep the vial in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after "EXP". The expiry date refers to the last day of that month.

Shelf-life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Cystic ovaries: In the treatment of cystic ovaries, the condition of ovarian follicular cysts should be diagnosed by rectal palpation revealing the presence of persisting follicular structures with a diameter over 2.5 cm and should be confirmed by the use of plasma or milk progesterone assay.

Product should be administered at least 14 days after calving due to the absence of receptivity of the hypophysis before that time.

For induction and synchronisation of oestrus and ovulation in Fixed Time Artificial Insemination (FTAI) protocols, the product should be administered at least 35 days after calving. The response of cows and heifers to synchronisation protocols is influenced by the physiological state at the time of treatment. Responses to treatment can vary either across herds or across cows within herds. However, the percentage of cows displaying oestrus within a given period is usually greater than in untreated cows and the subsequent luteal phase is of normal duration.

For protocol that only includes $PGF_{2\alpha}$ recommended for cycling cows: To maximise conception rates of cows to be treated, the ovarian status should be determined and regular cyclic ovarian activity confirmed. Optimal results will be achieved in healthy normally-cycling cows.

Animals in poor condition, whether from illness, inadequate nutrition, or other factors, may respond poorly to treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Care should be taken when handling the product to avoid self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Accidental spillage on the skin or eyes should be washed off with plenty of water.

Gonadorelin is a Gonadotropin Releasing Hormone (GnRH) analogue which stimulates the re-lease of sex hormones. The effects of accidental exposure to GnRH analogues in pregnant women or in women with normal reproductive cycles are unknown; therefore it is recommended that pregnant women should not administer the product, and that women of child-bearing age should administer the product with caution.

People with known hypersensitivity to GnRH analogues and benzyl alcohol, should avoid contact with the veterinary medicinal product.

Pregnancy and lactation:

Not indicated for use during pregnancy.
No contraindications have been described during lactation.

Overdose (symptoms, emergency procedures, antidotes):

Up to 5 times the recommended dose and in a regimen extended from one to three daily administrations, no measurable signs of either local or general clinical intolerance were observed.

Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{Month YYYY}

15. OTHER INFORMATION

Package sizes:

Cardboard box with 1 vial of 6 ml
Cardboard box with 1 vial of 20 ml
Cardboard box with 1 vial of 50 ml
Cardboard box with 1 vial of 100 ml
Cardboard box with 10 vials of 6 ml.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.