SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ACEGON 50 micrograms/ml solution for injection for cattle.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Gonadorelin .....50 µg
(equivalent to 52.5 µg of gonadorelin acetate)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E 1519)	9 mg
Potassium dihydrogen phosphate	
Dipotassium hydrogen phosphate	
Sodium chloride	
Water for injections	

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

3. CLINICAL INFORMATION

3.1 Target species

Cattle (cow and heifer).

3.2 Indications for use for each target species

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.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any excipients.
Do not use for shortening of oestrus during infectious diseases and other relevant disorders.

3.4 Special warnings

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.
The veterinary medicinal 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 veterinary medicinal 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

Gonadorelin is a Gonadotropin Releasing Hormone (GnRH) analogue which stimulates the release 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 veterinary medicinal product with caution.

Care should be taken when handling the veterinary medicinal 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.
Since GnRH analogues can be absorbed through the skin and benzyl alcohol may cause mild local irritation, care should be taken to avoid skin and eye contact. In case of skin and/or eyes contact, rinse immediately and thoroughly with plenty of water.

GnRH analogues and benzyl alcohol may cause hypersensitivity (allergy). People with known hypersensitivity to GnRH analogues or benzyl alcohol, should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy
Not applicable.

Lactation
Can be used during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

A synergistic effect occurs in case of combined administration of FSH.

3.9 Administration routes and dosage

Intramuscular use.

- **Treatment of ovarian follicular cysts**: 100-150 micrograms of gonadorelin (as acetate) per animal (i.e. 2- 3 ml of the veterinary medicinal 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 veterinary medicinal 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:

In cycling cows:

- Day 0 Inject 100 micrograms of gonadorelin (as acetate) per animal (2 ml of the veterinary medicinal product)
- Day 7 Inject $PGF_{2\alpha}$ or analogue (luteolytic dose)
- Day 9 Inject 100 micrograms of gonadorelin (as acetate) per animal (2 ml of the veterinary medicinal 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 veterinary medicinal product)
- Day 7 Inject $PGF_{2\alpha}$ or analogue (luteolytic dose)
- Artificial insemination and injection of 100 micrograms of gonadorelin (as acetate) per animal (2 ml of the veterinary medicinal product) 60–72 hours later, or at observed oestrus if sooner.

In cycling and non-cycling cows and heifers:

- Insert intravaginal progesterone releasing device for 7-8 days.
- Inject 100 micrograms of gonadorelin (as acetate) per animal (2 ml of the veterinary medicinal product) at progesterone device insertion.
- Inject a luteolytic dose of $PGF_{2\alpha}$ 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 veterinary medicinal product) 36 hours after progesterone releasing device removal and FTAI 16 to 20 hours later.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

At 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable

3.12 Withdrawal periods

Meat and offal: Zero days.
Milk: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QH01CA01

4.2 Pharmacodynamics

Gonadorelin (as acetate) is a synthetic gonadorelin ("Gonadotropin Releasing Hormone" GnRH) physiologically and chemically identical to the natural gonadorelin released by the hypothalamus in mammalian species.
Gonadorelin stimulates the synthesis and release of the pituitary gonadotropins, luteinizing hormone (LH) and follicle stimulating hormone (FSH). Its action is mediated by a specific plasma membrane receptor. Only 20% GnRH receptor occupancy is required to induce 80% of the maximum biological response. The binding of GnRH to its receptor activates protein kinase C (PKC) and also mitogen-activated protein kinase (MAPK) cascades which provide an important link for the transmission of signals from the cell surface to the nucleus allowing synthesis of the gonadotropin hormones.
Repeat breeding may be affected by multiple factors, including feeding and husbandry practices. Also, one of the most prominent findings in repeat breeding animals is the delayed and smaller preovulatory LH surge leading to delayed ovulation. Injection of GnRH during oestrus increases the spontaneous LH peak and prevents delay in ovulation in repeat breeding animals.

4.3 Pharmacokinetics

<u>Absorption</u>
After intramuscular administration in cows, gonadorelin is rapidly absorbed from the injection site, with a plasma half-life of approximately 20 minutes.

Distribution
An increase in the level of LH is detected thirty minutes after the administration, demonstrating fast distribution to the adenohypophysis.
Metabolism
The compound is rapidly metabolized into smaller inactive peptides and amino acids.
Elimination
The main excretion route is renal, although a significant proportion is also excreted in expired air.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf-life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25 ºC.

5.4 Nature and composition of immediate packaging

Type II colourless glass vials and type I bromobutyl rubber stoppers and aluminium cap.

Pack 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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios SYVA S.A.

7. MARKETING AUTHORISATION NUMBER

Vm 31592/4005

8. DATE OF FIRST AUTHORISATION

19 July 2011

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

August 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Approved 20 October 2025

Gavin Hall