PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Cardboard box with 1 vial of 6, 20, 50, 100 ml and cardboard box with 10 vials of 6 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Acegon 50 micrograms/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Gonadorelin 50 µg/ml.
(equivalent to 52.5 µg of gonadorelin acetate)

3. PACKAGE SIZE

6 ml/
20 ml
50 ml
100 ml
10 x 6 ml

4. TARGET SPECIES

Cattle (cow and heifer)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp {mm/yyyy}
Once broaching use within: 28 days.
Once broached, use by _____.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 ºC.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios SYVA S.A.

14. MARKETING AUTHORISATION NUMBER

Vm 31592/4005

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{50 ml/100 ml vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Acegon 50 micrograms/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Gonadorelin 50 µg/ml
(equivalent to 52.5 µg of gonadorelin acetate)

3. TARGET SPECIES

Cattle (cow and heifer)

4. ROUTES OF ADMINISTRATION

Intramuscular use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: zero days.
Milk: zero hours.

6. EXPIRY DATE

Exp{mm/yyyy}
Once broached used within: 28 days.
Once broached, use by_____

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 ºC.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios SYVA, S.A.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{6 ml /20 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Acegon

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Gonadorelin 50 µg/ml
(equivalent to 52.5 µg of gonadorelin acetate)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}
Once broached use within: 28 days.
Once broached, use by_____

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Acegon 50 micrograms/ml solution for injection for cattle.

2. Composition

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

Excipients:
Benzyl alcohol (E1519) .....9 mg
Clear, colourless or almost colourless solution free from visible particles

3. Target species

Cattle (cow and heifer).

4. Indications for use

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 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.

6. Special warnings

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.

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.

Lactation:
Can be used during lactation.

Interaction with other medicinal products and other forms of interaction:
A synergistic effect occurs in case of combined administration of FSH.

Overdose:
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 are observed.

Special restrictions for use and special conditions for use:

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

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, please contact, in the first instance, your veterinary. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes 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 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.

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.

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 immediate packaging: 28 days.

12. Special precautions for disposal

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 material derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 31592/4005

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

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

Local representatives and contact details to report suspected adverse reactions:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
Tel: +44 (0) 345 300 8034
E-mail: customersupportuk@zoetis.com

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

17. Other information

POM-V

Approved 20 October 2025
Gavin Hall