## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VeteCorH 1000 IU/ml lyophilisate and solvent for solution for injection for cattle, horses, sheep, goats, pigs, cats and dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of lyophilisate contains:

**Active substances:**
Chorionic Gonadotrophin……5000 IU

**Excipients:**

| **Qualitative composition of excipients and other constituents** |
|---|
| Mannitol |
| Sodium dihydrogen phosphate dihydrate (E-339(i)) |
| Disodium phosphate dihydrate (E-339(ii)) |
| Sodium hydroxide |
| Phosphoric acid, concentrated |

Each vial of solvent (5 ml) contains:

**Excipients:**

| **Qualitative composition of excipients and other constituents** |
|---|
| Sodium dihydrogen phosphate dihydrate (E-339(i)) |
| Disodium phosphate dihydrate (E-339(ii)) |
| Sodium hydroxide |
| Phosphoric acid, concentrated |
| Water for injection |

Once reconstituted, 1 ml of solution contains 1000 IU Chorionic Gonadotrophin

Lyophilisate and solvent for solution for injection

Lyophilisate: white or almost white powder
Solvent: clear and colourless solution

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle, horses, sheep, goats, pigs, cats and dogs.

### 3.2 Indications for use for each target species

Cattle, horses, pigs, sheep, goats, dogs and cats:

- In females: induction of ovulation (e.g. follicular cysts, delayed ovulation, anovulation).
- In males: stimulation of libido

Foals, puppies:

- Treatment of inguinal cryptorchidism.

### 3.3 Contraindications

Do not use in animals suffering from cancer and tumours which respond to/depend on sex hormones.
Do not use in cases of hypersensitivity to the active substance(s) or to any of the excipient(s).

### 3.4 Special warnings

As with all products containing proteins, anaphylactoid reactions may occur in rare cases. Treatment with adrenaline and glucocorticoids should be instituted promptly.
In mares, repeated chorionic gonadotropin (hCG) treatments may elicite formation of antibodies leading to reduced treatment responses.
For effective induction of ovulation in mares, the ovarian follicle should have reached a diameter of 30-35 mm.
As cryptorchidism may be inherited and efficacy of hormonal treatment is limited, chorionic gonadotrophin (hCG) in dogs and foals should be administered only after a thorough benefit/risk assessment by the veterinarian.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:
Intravenous injection should be given slowly.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product can provoke eye or skin irritation.
Studies performed with laboratory animals have shown dose-dependent teratogenic effects and testicular necrosis after subcutaneous injection.

People with known hypersensitivity to hCG should avoid contact with the veterinary medicinal product.
Avoid contact with skin.
The veterinary medicinal product should not be administered by pregnant women or whose pregnancy status is unknown.
Care should be taken to avoid accidental self-injection.
Wash hands after use.

In case of accidental spillage onto eye or skin, rinse immediately with plenty of water.
If accidental self-injection occurs, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Cattle, horses, sheep, goats, pigs, cats and dogs.

| | |
|---|---|
| Rare<br>(1 to 10 animals / 10 000 animals treated): | Anaphylaxis.[1] |

[1] immediate after injection. Depending on the course and severity of symptoms, adrenalin injection or glucocorticosteroids administration are indicated as a standard treatment after the onset of anaphylactic reaction.

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

This veterinary medicinal product can be used in pregnant and lactating females.

### 3.8 Interaction with other medicinal products and other forms of interaction

None known.

### 3.9 Administration routes and dosage

For intramuscular or slow intravenous use.

Reconstitute the solution for injection with the solvent provided and ensure its complete reconstitution just prior to its use.

The reconstituted solution appears clear and colourless.

Cows and horses: 1500 to 5000 IU (corresponding to 1.5 to 5mL of the reconstituted solution)
Ovine, caprine and porcine: 500 to 1500 IU (corresponding to 0.5 to 1.5mL of the reconstituted solution)
Dogs and cats: 100 to 500 IU (corresponding to 0.1 to 0.5mL of the reconstituted solution)

In some cases, it may be necessary to repeat injections as recommended by the veterinarian.

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

None known.

### 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

Cattle, horses, sheep and goats:
Meat and offal: Zero days.

Milk: Zero hours.

Pigs:

Meat and offal: Zero days.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QG03GA01

### 4.2 Pharmacodynamics

The human chorionic gonadotrophin (hCG) is a large glycoprotein composed of two non-covalently associated alpha and beta subunits.
The extensive glycosylation of the CTP tail of the beta subunit of hCG results in its extended half-life which reaches 27h in pigs. This medicine replaces the ante-pituitary gonadotropin LH effect (Luteinizing Hormone).
hCG increases follicle maturation by stimulating androgen production by the theca cells and causes ovulation of the dominant follicle. It also stimulates formation and activity of the corpus luteum.

In the male, hCG stimulates the production of androgens by its action on the interstitial tissue that stimulates the libido and the development of secondary sexual characteristics.

### 4.3 Pharmacokinetics

Following intramuscular or intravenous injection, hCG is rapidly absorbed. After intramuscular injection, bioavailability is high. $C_{max}$ is reached within 8 hours in all target species. In bovine, peak hCG concentration in plasma of cows is achieved 45 minutes after intravenous injection of a dose of 3000 IU.
The elimination half-life of hCG is about 10 hours in cattle, and 27 h in pigs.

## 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 lyophilisate as packaged for sale: 3 years.
Shelf life of the solvent as packaged for sale: 5 years.
Shelf life after reconstitution according to directions: 24 hours.

### 5.3 Special precautions for storage

Store below 25 °C.

After reconstitution: store refrigerated (2 °C – 8 °C).

### 5.4 Nature and composition of immediate packaging

Lyophilisate product:
Colourless glass Eur. Ph. type I vials closed with grey bromobutyl rubber stoppers and blue FLIP-OFF seal and aluminium caps.

Solvent:

Colourless glass Eur. Ph. type I vials closed with grey bromobutyl rubber stoppers and blue FLIP-OFF seal and aluminium caps.

Package sizes:
Box of 1 vial of lyophilisate + Box of 1 vial of 5 ml of solvent
Box of 2 vials of lyophilisate + Box of 2 vials of 5 ml of solvent
Box of 5 vials of lyophilisate + Box of 5 vials of 5 ml of solvent

Box of 1 vial of lyophilisate and 1 vial 5 ml of solvent
Box of 2 vials of lyophilisate and 2 vials 5 ml of solvent
Box of 5 vials of lyophilisate and 5 vials of 5 ml of solvent

Not all pack sizes may be marketed.

### 5.5 Special precautions for the disposal of unused veterinary medicinal products 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 CALIER S.A.,

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA10665/010/001

## 8. DATE OF FIRST AUTHORISATION

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

23 April 2025

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).