1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chorulon 1500 IU lyophilisate and solvent for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of lyophilisate contains:

Active substance:

Gonadotrophin, Chorionic Ph. Eur. 1500 IU

Excipients:

Qualitative composition of excipients and other constituents
Mannitol
Sodium Dihydrogen Phosphate Dihydrate
Disodium Phosphate Dihydrate

Lyophilisate: White to off-white powder.

Each (5ml) vial of solvent contains:

Excipients:

Qualitative composition of excipients and other constituents
Water for Injections
Sodium Dihydrogen Phosphate Dihydrate
Disodium Phosphate Dihydrate

Solvent: Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, dogs.

3.2 Indications for use for each target species

Improvement of conception rate (cow), induction of ovulation (mare, bitch), cystic ovaries with irregular oestrus cycle, nymphomania, or absence of oestrus (cow), anoestrus (mare, bitch), delayed ovulation/prolonged oestrus (bitch), cryptorchidism (male dog), deficiency in libido (male dog).

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

As with all protein preparations, anaphylactic reactions might occur very seldomly.

Adrenaline (1:1000) can be injected intravenously or intramuscularly when such symptoms appear.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle, horses, dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Anaphylaxis[1]

[1]May occur shortly after injection, as with all protein preparations, Adrenaline injection (1:1000) given intravenously or intramuscularly when symptoms appear is the standard treatment. The administration of corticosteroids may also be indicated.

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 the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not use during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intramuscular **(i.m.)** and intravenous **(i.v.)** use.

Animal species	**Indication**	**Dosage and administration**
Cow, heifer	Improvement of conception rate Cystic ovarian disease (anoestrus, prolonged oestrus, nymphomania)	1500 IU **i.m.** or **i.v**. at A.I. or mating 3 000 IU **i.v.**
Mare	Suboestrus (follicles >2 cm diameter) Induction of ovulation (follicles ≥ 3.5 cm diameter)	1500 - 3000 IU **i.m**. or **i.v.,** repeat if necessary after 2 days 1500 - 3 000 IU **i.m.** or **i.v**. 24 hours before A.I. or mating
Bitch	Anoestrus	After pre-treatment with PMSG

	Delayed ovulation, prolonged oestrus	(Folligon), 500 IU **i.m.** or **i.v.** at first day of oestrus 100 - 800 IU/day **i.m**., repeat treatment until vaginal discharge disappears
Male dog	Cryptorchidism Deficiency in libido	100 - 500 IU **i.m**. twice weekly up to 6 weeks 100 - 500 IU **i.m.** 6 - 12 hours before mating

Reconstituted Product: Clear, colourless solution.

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

No specific treatment or antidote recommended.

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

Horses:
Meat and offal: Zero days.
Milk: Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QG03GA01

4.2 Pharmacodynamics

The active ingredient of Chorulon, Gonadotrophin, Chorionic Ph. Eur. (hCG), is a complex glycoprotein with luteinising hormone (LH) activity. In the female hCG can be used to promote maturation of the follicle, ovulation and the formation of the corpus luteum. In the male, chorulon stimulates the production of testosterone, and thus influences the development and maintenance of primary and secondary male sex characteristics.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after reconstitution according to directions: 24 hours.

5.3 Special precautions for storage

Do not store above 25 °C.
Keep vials in the outer carton in order to protect from light. Store the reconstituted product between 2 °C and 8 °C.

5.4 Nature and composition of immediate packaging

Clear, glass Type I (Ph. Eur.) vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap.
Packs contain 5 vaccine vials and 5 solvent vials (5 ml each).

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

Intervet Ireland Limited.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/021/001

8. DATE OF FIRST AUTHORISATION

01/10/1989

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

29/07/2025

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).