Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Chorulon 1500 IU Powder and solvent for solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each powder vial contains:

Active Substance

human Chorionic Gonadotrophin	1500 IU

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, horse, dog

4.2 Indications for use, specifying the target species

Therapeutic indications: 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).

4.3 Contraindications

Do not use in known cases of hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

As with all protein preparations, anaphylactic reactions might occur very seldomly.
Adrenaline (1 : 1000) can be injected i.v. or i.m. when such symptoms appear.

4.5 Special precautions for use

Special precaution(s) for use in animals

None.

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

None.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

Not indicated for use during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

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 $\geq$ 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 delayed ovulation, prolonged oestrus	after pre-treatment with PMSG (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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No specific treatment or antidote recommended.

4.11 Withdrawal Period(s)

Meat and offal: Zero days
Milk: Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Gonadtropins
ATCvet code: QG03GA01

5.1 Pharmacodynamic properties

The active ingredient of Chorulon, human Chorionic Gonadotrophin (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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol
Sodium Dihydrogen Phosphate Dihydrate
Disodium Phosphate Dihydrate
Water for Injections

6.2 Incompatibilities

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

6.3 Shelf-life

Shelf-life of the freeze dried powder as packaged for sale: 3 years. Shelf-life of the solvent as packaged for sale: 3 years. Shelf-life after reconstitution according to directions: 24 hours

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.
The reconstituted product should also be stored between 2° and 8°C.
Keep container in outer carton.

6.5 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).

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/021/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1989
Date of last renewal: 21st August 2009

10 DATE OF REVISION OF THE TEXT