SUMMARY OF PROUDCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chorulon 1500 iu, powder and solvent for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of active contains:

Active substance:
Chorionic gonadotrophin 1500 iu

Each vial of solvent contains 5 ml of a sterile buffered solvent for reconstitution.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection
White powder and clear colourless solution.
Reconstituted solution is colourless.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horses and dogs

4.2 Indications for use, specifying the target species

The product can be used in the following fertility problems in domestic animals:

- cases of repeated failure of conception in cows and heifers
- induction of ovulation in mares and bitches
- cases of cystic ovaries in cows and heifers
- anoestrus in mares and bitches
- delayed ovulation, prolonged pro-oestrus in bitches
- deficiency in libido in male dogs

4.3 Contra-indications

None

4.4 Special warning for each target species

None

4.5 Special precautions for use

(i) Special precautions for use in animals

None

(ii) Special precautions to be taken by the person administering the medicinal product to the animals

Care should be taken to avoid accidental self-injection; if accidental self-injection occurs, seek medical advice immediately and show the doctor this label.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

In rare cases, as with all protein preparations, anaphylactoid incidents may occur shortly after injection. Adrenalin injection (1:1,000) given intravenously or intramuscularly when symptoms appear is the standard treatment. The administration of corticosteroids may also be indicated.

4.7 Use during pregnancy or lactation

Not applicable

4.8 Interaction with other medicinal products and other forms of interaction

None

4.9 Amounts to be administered and administration route

Reconstitute with the solvent provided, ensuring the freeze dried plug is fully dissolved. Administer by intramuscular or intravenous injection, observing the usual aseptic precautions.

Cow and heifer:
Repeated failure of conception:
1500 iu - i.m. or i.v. at AI or mating

Cystic ovarian disease (anoestrus, prolonged oestrus, nymphomania):
3000 iu - i.v.

Enhancement of luteal function

1500 iu i.m. 12 days after insemination or mating

Mare:

Suboestrus (follicles > 2 cm in diameter)

1500 - 3000 iu - i.m. or i.v., repeat after 2 days if necessary

Induction of ovulation:

1500 - 3000 iu - i.m. or i.v 24 hours before AI or mating

Bitch:

Anoestrus:

500 iu - i.m. or i.v. at first day of oestrus after pretreatment with PMSG 20 iu/kg s.c. daily for 10 days

Delayed ovulation, prolonged pro-oestrus:

100 - 800 iu/day - i.m., repeating treatment until vaginal bleeding disappears. Mate on behavioural oestrus.

Male dog:

Deficiency in libido:

100 -500 iu - i.m. twice weekly for up to 6 weeks, but if this is not possible then 100 -500 iu i.m. 6-12 hours before mating may give a temporary effect.

Further information

The product has been used in cases of cryptorchidism in the dog prior to castration (100-500 iu i.m. twice weekly for up to 6 weeks). Treatment may be effective in some cases provided that the inguinal canal is patent, and that therapy commences early.

The product has intrinsic LH-like activity. Injection of 1500 iu 12 days after heat in cattle enhances the active life of the corpus luteum by 2 to 3 days, resulting in increased progesterone and suppression of oestradiol production. These changes are consistent with those observed after GnRH use at day 11-13 of the cycle which are believed to be responsible for the increased pregnancy rates seen after such use. The mode of action is however different, since the product does not rely on first stimulating an endogenous LH peak. This use of the product has not been investigated in the field.

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

No specific treatment or antidote recommended.

4.11 Withdrawal periods for the various foodstuffs, including those for which the withdrawal period is zero

Cattle: Meat – Zero days
Milk – Zero hours

Horses: Meat – Zero days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Sex hormones and modulators of the genital system
ATCvet code: QG03GA01

5.1 Pharmacodynamic properties

Chorulon is a freeze-dried presentation of hCG together with solvent for reconstitution. hCG is a gonadotrophin. It 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. hCG increases follicle maturation by stimulating androgen production by the cal cells and causes ovulation of the dominant follicle . Owing to its long half life, it also stimulates formation and function of the corpus luteum.
In the male, hCG stimulates formation of testosterone, thus influencing the development and maintenance of primary and secondary male sexual characteristics.

5.2 Pharmacokinetic properties

Following i.m or i.v. injection, hCG is rapidly absorbed. Bioavailability following i.m. injection is high. Cmax is reached within 8hours in all target species. More specifically, peak hCG concentration (0.05 IU/ml) in plasma of cows is achieved 45 minutes after i.v. injection of a dose of 3000 IU. The elimination half-life of hCG is about 10 hours in cattle, and 27h in pigs.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol
Sodium Phosphate Dihydrate
Sodium Dihydrogen Phosphate Dihydrate
Sodium Acid Phosphate Dihydrate
Sodium Hydroxide or Phosphoric acid (for pH adjustment)
Water for injection
Nitrogen

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after dilution or reconstitution according to directions: 24 hours at 2-8 ˚C.

6.4 Special precautions for storage

Storage before reconstitution

Do not store above 25 ˚C.

Storage after reconstitution

Protect from light.
Any product not used immediately after reconstitution should be stored refrigerated between +2˚C and +8˚C. Reconstituted product remaining 24 hours after preparation should be discarded safely.
This product does not contain an antimicrobial preservative.
Avoid the introduction of contamination during use.

6.5 Nature and composition of immediate packaging

This product does not contain an antimicrobial preservative.

Powder: Clear, Glass Type I vials with halobutyl rubber bung secured with an aluminium collar containing 1500 iu Chorionic gonadotrophin.
Solvent: Clear, Glass Type I vials with halobutyl rubber bung secured with an aluminium collar containing 5 ml buffered sterile solvent.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4090

9. DATE OF FIRST AUTHORISATION OF THE AUTHORISATION

18 May 1994

10. DATE OF REVISION OF TEXT

November 2024

Gavin Hall
Approved: 22 November 2024