



#### **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**

MSD Animal Health UK Limited  
Walton Manor  
Walton  
Milton Keynes  
Buckinghamshire  
MK7 7AJ

### **8. MARKETING AUTHORISATION NUMBER**

Vm 01708/4301

### **9. DATE OF FIRST AUTHORISATION OF THE AUTHORISATION**

18 May 1994

**10. DATE OF REVISION OF TEXT**

April 2021

Approved: 01/04/21

A handwritten signature in black ink that reads "D. Austin". The signature is written in a cursive style with a horizontal line extending from the end of the name.