PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CHORULON 1500 IU Powder and solvent for solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Human Chorionic Gonadotrophin 1500 IU per vial

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection

4. PACKAGE SIZE

5 vials with solvent

Contents:

5 vials each containing CHORIONIC GONADOTROPHIN 1500 IU

5 vials each containing 5 ml sterile buffered solvent.

5. TARGET SPECIES

Cattle, horses and dogs.

6. INDICATION(S)

Not applicable.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Freeze-dried powder for reconstitution with supplied solvent prior to use.

For administration to cattle, horses and dogs by IM or IV injection.

Read package leaflet for directions, disposal advice and warnings before use.

8. WITHDRAWAL PERIOD

Withdrawal periods:

Cattle Meat - Zero days

Milk - Zero hours

Horses meat: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet for directions, disposal advice and warnings before use.

Care should be taken to avoid accidental self-injection.

10. EXPIRY DATE

Expiry end of:

11. SPECIAL STORAGE CONDITIONS

Storage before reconstitution:

Do not store above 25 °C.

Protect from light.

Storage after reconstitution:

Any product not used immediately after reconstitution should be stored refrigerated between +2 °C and +8 °C.

Reconstituted product remaining after 24 hours after preparation should be discarded safely.

Keep container in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read package leaflet for directions, disposal advice and warnings before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

FOR ANIMAL TREATMENT ONLY.

POM-V

To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:

Intervet International B.V.

Wim de Körverstraat 35

5831 AN Boxmeer

The Netherlands

Distributor in N. Ireland:

INTERVET IRELAND Ltd.

Magna Drive, Magna Business Park

Citywest Road, Dublin 24

Manufacturers:

Intervet International B.V.

Boxmeer

The Netherlands

and

Intervet International GmbH

85716 Unterschleissheim

Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06376/4090

17. MANUFACTURER'S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
VIAL LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CHORULON 1500 IU powder and solvent for solution for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

CHORIONIC GONADOTROPHIN 1500 IU

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1500 IU

4. ROUTE(S) OF ADMINISTRATION

IM / IV

For administration to cattle, horses and dogs. Read package leaflet for directions, storage/disposal advice and warnings before use.

5. WITHDRAWAL PERIOD

Withdrawal periods: Cattle milk: Zero hours.

Cattle and horse meat: Zero days.

6. BATCH NUMBER

Batch no:

7. EXPIRY DATE

Expiry end of:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

FOR ANIMAL TREATMENT ONLY.

POM-V

To be supplied only on veterinary prescription

Keep out of the sight and reach of children.

Keep container in outer carton.

Once broached, use by:

MA Holder:

Intervet International B.V.

Wim de Körverstraat 35

5831 AN Boxmeer

The Netherlands

PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT LABEL

1. NAME OF THE DILUENT

SOLVENT FOR CHORULON 1500 IU powder and solvent for solution for injection

STERILE PHOSPHATE BUFFERED WATER FOR INJECTION

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 ml

3. ROUTES OF ADMINISTRATION

Read package leaflet for directions, storage precautions, disposal advice and warning before use.

4. STORAGE CONDITIONS

Keep container in outer carton.

5. BATCH NUMBER

Batch no:

6. EXPIRY DATE

Expiry end of:

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

FOR ANIMAL TREATMENT ONLY.

POM-V

To be supplied only on veterinary prescription

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Vm 06376/4090

MA Holder:

Intervet International B.V.

Wim de Körverstraat 35

5831 AN Boxmeer

The Netherlands

PACKAGE LEAFLET FOR:

Chorulon 1500 IU, powder and solvent for solution for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder

Intervet International B.V.

Wim de Körverstraat 35

5831 AN Boxmeer

The Netherlands

Manufacturer for the batch release

Intervet International B.V.

Wim de Körverstraat 35

5831 AN Boxmeer

The Netherlands

or

Intervet International GmbH

Feldstrasse 1a

85716 Unterschleissheim

Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chorulon 1500 IU, powder and solvent for solution for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

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.

White powder and clear colourless solution. Reconstituted solution is colourless.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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.

7. TARGET SPECIES

Cattle, horses and dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Species	*Indication*	*Dosage and administration*
Cow, heifer	Repeated failure of conception	1500 IU- IM or IV at AI or mating
	Cystic ovarian disease (anoestrus, prolonged oestrus, nymphomania)	3000 IU – IV
	Enhancement of luteal function	1500 IU - IM 12 days after insemination or mating

Mare	Suboestrus (follicles > 2 cm in diameter) Induction of ovulation	1500 - 3000 IU - IM or IV, repeat after 2 days if necessary 1500-3000 IU - IM or IV 24 hours before AI or mating
Bitch	Anoestrus Delayed ovulation, prolonged pro-oestrus	500 IU - IM or IV at first day of oestrus after pretreatment with PMSG 20 IU/kg SC daily for 10 days 100-800 IU / day IM, repeating treatment until vaginal bleeding disappears. Mate on behavioural oestrus
Male dog	Deficiency in libido	100-500 IU - IM twice weekly for up to 6 weeks, but if this is not possible then 100-500 IU IM. 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 IM 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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

Cattle: Meat – Zero days

Milk – Zero hours

Horses: Meat – Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

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. Keep the container in outer carton.

12. SPECIAL WARNING(S)

USER WARNINGS

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

15. OTHER INFORMATION

For animal treatment only.

Pack sizes

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.

Legal category

POM-V To be supplied on veterinary prescription only.

Marketing authorisation number

Vm 06376/4090

Distributor in N. Ireland:

Intervet Ireland Ltd.

Magna Drive, Magna Business Park

Citywest Road

Dublin 24

Ireland

Gavin Hall

Approved: 22 November 2024