CYSTORELINE®

Product information

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These pages are general information pages. No guarantee is given as to the completeness of the information contained or its compliance with national regulatory requirements. Users should consult the local site of their countries to obtain information that complies with applicable national regulations.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cystoreline

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Gonadorelin (as diacetate tetrahydrate) ..... 0.05 mg

Excipients:

Benzyl alcohol (E1519) ..... 15.0 mg

For the full list of excipients, see section 6.1 “List of excipients”.

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1 | Target species

Bovine and rabbits.

4.2 | Indications for use, specifying the target species

In cows:

- Induction of ovulation in repeat breeding female.
- Treatment of follicular cyst.
- Induction and synchronization of oestrus and ovulation in combination with prostaglandin F2a (PGF2a) or analogue with or without progesterone as part of the Fixed-Time Artificial Insemination (FTAI) protocol.

In female rabbits:

- Induction of ovulation prior artificial insemination.

4.3 | Contraindications

None.

4.4 | Special warnings for each target species

Response to the timing protocol may be influenced by the physiological status of dairy cows at the time of treatment, including cow age, body condition, and calving interval.

The responses to treatment are not uniform, either at the flock level or at the cow level in the flock.

When a period of treatment with progesterone is included in the protocol, the percentage of cows with oestrus within a given time frame is generally greater than in untreated cows and the following luteal phase is of normal duration.

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 veterinary medicinal product to animals

Avoid contact with skin and eyes. In case of accidental contact with eyes, rinse with water. After contact with skin, wash immediately the area exposed to water and soap, as GnRH analogues may be absorbed through the skin.

The effects of accidental exposure of GnRH analogues in pregnant women and in women with normal reproductive cycles are unknown, therefore it is recommended that pregnant women should not administer the product and that women of child-bearing age should administer the product with caution.

People with known hypersensitivity to GnRH analogues should avoid contact with the veterinary medicinal product.

Upon administration of the drug, ensure that the animals are subject to a good compression and the needle is protected until the time of injection, in order to avoid accidental injection. In case of accidental self injection, seek medical advice and show the package insert or label.

iii Other precautions

None.

4.6 | Adverse reactions (frequency and seriousness)

None.

4.7 | Use during pregnancy, lactation or lay

Product safety during gestation current administration has not been demonstrated. The drug may be used during lactation.

4.8 | Interaction with other medicinal products and other forms of interaction

Not known.

4.9 | Amounts to be administered and administration route

In cows: Intramuscular route.

100 µg of gonadorelin per animal, ie 2 ml of solution in a single administration.

Judgement of protocol to be used should be made by the veterinarian responsible for treatment, on the basis of the treatment objectives of the individual herd or cow. The following protocols have been evaluated and can be used:

Induction of estrus and synchronization of ovulation in association with prostaglandin F2a (PGF2a) or the analogue:

- Day 0: first injection of gonadorelin (2 ml of the product).
- Day 7: injection of prostaglandin (PGF2a) or analogue.
- Day 9: second injection of gonadorelin (2 ml of the product) should be done.

The animal must be inseminated within 16-20 hours after the last injection of the product or at the time of oestrus if observed earlier.

Induction of estrus and synchronization of ovulation in association with prostaglandin F2a (PGF2a) or analogue and a progesterone releasing intravaginal device:

The following FT AI protocols have been frequently reported in the literature:

- Insert the vaginal progesterone delivery system for 7 days.
- Inject gonadorelin (2 ml of the product) at the progesterone releasing intravaginal device insertion.
- Inject a prostaglandin (PGF2a) or analogue 24 hours prior to device removal.
- Insemination (FT Al) 56 hours after removal of the vaginal delivery system or,
- Inject gonadorelin (2 ml of the product) 36 hours after progesterone releasing intravaginal device removal and inseminate (FTAI) 16 to 20 hours later.

Induction of delayed ovulation:

100 µg of gonadorelin per animal, ie 2 ml of solution in a single administration, intramuscularly, the day of insemination, or between the 13th and 15th day of the cycle.

Treatment of follicular cystic syndrome:

100 µg of gonadorelin per animal, ie 2 ml of solution, in a single intramuscular administration.

About a week after treatment, the presence of a corpus luteum becomes detectable on the surface of the ovary during a rectal palpation. If this is not the case, or if new follicular cysts have appeared, it is necessary to repeat the treatment. Insemination or breeding can be done during the first oestrus after treatment, usually 20 days after the injection.

In female rabbits:

10 µg of gonadorelin per animal, ie 0.2 ml of solution in a single administration just before artificial insemination by intramuscular route.

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

Not known.

4.11 | Withdrawal period(s)

Meat and offal: zero days

Milk: zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Gonadotropin-releasing hormones.
ATCvet code: QH01CA01

5.1 | Pharmacodynamic properties

Gonadorelin is a synthetic analogue of the Gonadotropin Releasing Hormone (GnRH). Its mode of action is identical as the one of natural GnRH.
Gonadorelin stimulates the synthesis and release of the pituitary gonadotropins, luteinizing hormone (LH) and follicle stimulating hormone (FSH).
The role of these hormones LH and FSH is decisive in the maturation of the preovulatory follicle. Gonadorelin induces regression of cystic follicles or ovulation, allowing the emergence of a new follicular wave.

5.2 | Pharmacokinetic particulars

After intramuscular administration, the GnRH analogues are quickly absorbed and accumulate mainly in the liver, kidney and pituitary.

They are then metabolized enzymatically with the production of compounds without pharmacological activity. These compounds are subsequently excreted in urine.

6. PHARMACEUTICAL PARTICULARS

6.1 | List of excipients

Benzyl alcohol (E1519)
Potassium dihydrogen phosphate
Dipotassium phosphate
Sodium chloride
Water for injections

6.2 | Major incompatibilities

None.

6.3 | Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months (2ml vial).
Shelf life of the veterinary medicinal product as packaged for sale: 2 years (4, 10, 20 and 50 ml vials).
Shelf-life after first opening the immediate packaging: 28 days.

6.4 | Special precautions for storage

Do not store above 25°C.

6.5 | Nature and composition of immediate packaging

Material of the primary packaging:
Colourless glass vial type I (2 ml, 4 ml)
Colourless glass vial type II (10ml, 20 ml and 50 ml)
Chlorobutyl stopper

Pack sizes:
Carboard box containing 10 vials of 2 ml
Carboard box containing 1 vial of 4 ml
Carboard box containing 1 vial of 10 ml
Carboard box containing 1 vial of 20 ml
Carboard box containing 1 vial of 50 ml

Not all pack sizes may be marketed.

6.6 | Special precautions for the 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.