

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CIDR 1.38g

Vaginal Delivery System for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s):

Each device contains Progesterone. 1.38 g.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Vaginal delivery system.

A "T" shape device consists of progesterone impregnated silicone elastomer skin moulded over an inert nylon spine.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (cows and heifers).

4.2 Indications for use, specifying the target species

For the control of the oestrous cycle in cycling cows and heifers, including:

- Synchronisation of oestrus in groups of animals including fixed time artificial insemination (FTAI) programmes.
- Synchronisation of donor and recipient animals for embryo transfer.

To be used in combination with prostaglandin F2 α or analogue.

Use as recommended normally results in oestrus 48-96 hours after device removal with the majority of animals showing oestrus within 48-72 hours.

For induction and synchronisation of oestrus in Fixed Time Artificial Insemination (FTAI) protocols:

- In cycling cows and heifers. To be used in combination with prostaglandin F2 α (PGF2 α) or analogue.
- In cycling and non-cycling cows and heifers. To be used in combination with Gonadotropin releasing hormone (GnRH) or analogue and PGF2 α or analogue.
- In non-cycling cattle. To be used in combination with PGF2 α or analogue and equine chorionic gonadotrophin (eCG).

4.3 Contraindications

Do not use:

- in cows or heifers, with abnormal or immature genital tracts, or with genital infections.
- in pregnant cattle.
- within the first 35 days after calving.

4.4 Special warnings for each target species

The progesterone treatment alone, according to dosage regimen proposed, is not sufficient to induce oestrus and ovulation in all cycling females. Progesterone based breeding protocols are reproduction management tools and should not replace adequate feeding and general health management. The choice of a specific protocol should be based on the requirements of the individual herd and it is advisable to examine cycling ovarian activity before using the progesterone treatment.

The response of cows and heifers to progesterone based synchronisation protocols is influenced by the physiological state at the time of treatment.

Responses to treatment can vary either across herds or across cows within herds.

However, the percentage of cows displaying oestrus within a given period is usually greater than in untreated cows and the subsequent luteal phase is of normal duration.

4.5 Special precautions for use

Special precautions for use in animals

Animals in poor condition, whether from illness, inadequate nutrition, or other factors, may respond poorly to treatment.

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

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product during insertion and removal. Insert the device using the applicator.

Ensure correct administration; including use of a non-irritant antiseptic and lubrication (see section 4.9).

Wash hands and exposed skin with soap and water after use.

Do not eat, drink or smoke while handling the product.

4.6 Adverse reactions (frequency and seriousness)

Vaginal discharge associated with local irritation has been observed at removal of the insert. This discharge generally clears between the time of removal and insemination and has not been seen to affect conception rates following treatment.

4.7 Use during pregnancy, lactation or lay

Can be used during lactation.

The safety of the veterinary medicinal product has not been established, so do not use in pregnant cattle or within the first 35 days after calving. Laboratory studies in rat and rabbit, after intramuscular or subcutaneous administrations, and at repeated high doses of progesterone, have produced evidence of foetotoxic effects.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

1.38g of progesterone (1 device) per animal for 7- 9 days (depending on indication).

For synchronisation of oestrus and synchronisation of donor and recipient animals for embryo transfer:

One device should be inserted into the vagina of each cow or heifer to be treated. The vaginal insert should be left in position for 7 days with an injection of a luteolytic dose of prostaglandin F2 α or analogue administered 24 hours prior to removal. In animals that respond to treatment the onset of oestrus generally occurs within 1-3 days after removal of the insert. Cows should be inseminated within 12 hours of first observed oestrus.

For the induction and synchronisation of oestrus for Fixed Time Artificial Insemination (FTAI):

The following FTAI protocols have been commonly reported in the scientific literature and should be used:

In cycling cows and heifers:

- Insert one CIDR 1.38g into vagina for 7 days.
- Inject a luteolytic dose of PGF2 α or analogue 24 hours prior to device removal.
- FTAI 56 hours after removal of the device.

In cycling and non-cycling cows and heifers:

- Insert one CIDR 1.38g into vagina for 7- 8 days.
- Inject a dose of GnRH or analogue at CIDR 1.38g insertion.
- Inject a luteolytic dose of PGF2 α or analogue 24 hours prior to device removal.
- FTAI 56 hours after removal of the device, or
- Inject GnRH or analogue 36 hours after CIDR 1.38g removal and FTAI 16 to 20 hours later.

In non-cycling cows:

The following FTAI protocol should be used:

- Insert one CIDR 1.38g into vagina for 9 days.
- Inject a luteolytic dose of PGF2 α or analogue 24 hours prior to device removal.
- Inject eCG at CIDR 1.38g removal.
- FTAI 56 hours after removal of the device, or inseminate within 12 hours following first observed oestrus behaviour.

Administration

A device applicator should be used for administration, following the procedure described below:

1. Ensure that the applicator is clean and dipped in a non-irritant antiseptic solution before use.
2. Wearing sterile disposable plastic gloves, fold the arms of the device and load into the applicator. The arms of the device should protrude slightly from the end of the applicator. Care should be taken to avoid unnecessary or prolonged handling of the product to minimise transfer of the active substance to the operator's gloves.
3. Apply a small quantity of obstetrical lubricant to the end of the loaded applicator.

4. Lift the tail and clean the vulva and perineum.
5. Gently insert the applicator into the vagina, first in a vertical direction and then horizontally until some resistance is encountered.
6. Make sure the removal string is free, press the handle of the applicator and allow the barrel to move back towards the handle. This releases the arms of the device, which will then retain the device in the anterior vagina.
7. With the device correctly positioned, withdraw the applicator, leaving the removal string hanging from the vulva.
8. The applicator should be cleaned and disinfected before being used on another animal.

Removal

The device may be removed by gently pulling on the string. On occasions the string may not be visible from the outside of the animal, in such cases it may be located in the posterior vagina using a gloved finger. Withdrawal of the device should not require force. If any resistance is encountered a gloved hand should be used to ease removal.

If there is any difficulty in removal from the animal beyond that itemised above veterinary advice must be sought.

The device is intended for single use only.

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

Not applicable.

4.11 Withdrawal periods

Meat and offal: zero days.

Milk: zero hours.

During the treatment milk can be used for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Genito Urinary System and Sex Hormones

ATCVet code: QG03DA04

5.1 Pharmacodynamic properties

The vaginal delivery system delivers progesterone at a controlled rate across the vaginal mucosa into the blood stream. This suppresses the release of gonadotrophin releasing hormone and consequently luteinising hormone from the anterior pituitary inhibiting follicle maturation and so controlling the oestrous cycle. After removal of the device, circulating blood levels of progesterone fall precipitously within 6 hours, allowing follicle maturation, behavioural oestrus and ovulation.

5.2 Pharmacokinetic particulars

The pharmacokinetic profile of progesterone when administered as a single device was characterised by a maximum concentration (C_{\max}) in plasma of approximately 4.33 ng/ml achieved at 1.19 hours post-dosing (T_{\max}) and an Area Under the Curve (AUC_{∞}) of 19.47 ng/ml.hr. Peak concentrations were followed by a decline in systemic exposure with an apparent elimination half-life ($t_{1/2}$) of 0.298 hours. After removal of the device, circulating blood levels of progesterone fall precipitously within 6 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Silicone elastomer
Nylon spine
Polyester Tail

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Do not store above 30° C.

6.5 Nature and composition of immediate packaging

The devices are packed in heat-sealed low-density polyethylene sachets in units of 10 per sachet. Sachets are re-sealable (zip-line).

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.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

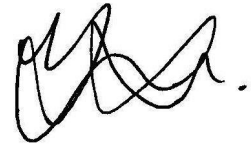
Vm 42058/4012

9. DATE OF FIRST AUTHORISATION

20 February 2008

10. DATE OF REVISION OF THE TEXT

November 2019

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 12 November 2019