1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CIDR 1.38 g vaginal delivery system for cattle
(*AT, BE, CZ, FI, FR, DE, HU, IE, IT, LU, NL, PL, PT, SL, SK, ES, UK(NI)*)

Relmont Vet 1.38 g vaginal delivery system for cattle
(*DK, NO, SE*)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each device contains:

Active substance:
Progesterone 1.38 g

Excipients:

Qualitative composition of excipients and other constituents
Silicone elastomer
Nylon spine
Polyester Tail

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

3. CLINICAL INFORMATION

3.1 Target species

Cattle (cows and heifers).

3.2 Indications for use for each 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 (PGF2α) or analogue.
- In cycling and non-cycling cows and heifers. To be used in combination with Gonadotrophin releasing hormone (GnRH) or analogue and PGF2α or analogue.
- In non-cycling cattle. To be used in combination with PGF2α or analogue and equine chorionic gonadotrophin (eCG).

3.3 Contraindications

Do not use in cows or heifers, with abnormal or immature genital tracts, or with genital infections.

Do not use in pregnant cattle.
Do not use within the first 35 days after calving.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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:
Progesterone is a potent steroid hormone and may cause adverse effects on the reproductive system in cases of high or prolonged exposure. As adverse effects on unborn children cannot be ruled out, pregnant women should avoid using this veterinary medicinal product.

The veterinary medicinal product may cause skin and eye irritation as well as allergic skin rashes.
Avoid accidental contact with the eyes. In case of accidental ocular exposure, flush the eyes thoroughly with water.
Persons administering the veterinary medicinal product should avoid contact with the silicone section; pregnant women should completely avoid handling the veterinary medicinal product.
The device should be inserted using the veterinary medicinal product specific applicator.
Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product during insertion and removal.
Ensure correct administration; including use of a non-irritant antiseptic and lubrication (see section 3.9).

Wash hands and exposed skin with soap and water after use.
Do not eat, drink or smoke while handling the veterinary medicinal product.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle (cows and heifers):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	vaginal discharge[1], vulva irritation / vaginal irritation[1]

[1] observed at removal of insert, this discharge generally clears between the time of removal and insemination and has not been seen to affect conception rates following treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.. .

3.7 Use during pregnancy, lactation or lay

Pregnancy:
The safety of the veterinary medicinal product has not been established during pregnancy. 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 shown evidence of foetotoxic effects.

Lactation:
Can be used during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Vaginal use.
1.38 g 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 F2α 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 1.38 g into vagina for 7 days.
- Inject a luteolytic dose of PGF2α 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 1.38 g into vagina for 7- 8 days.
- Inject a dose of GnRH or analogue at CIDR 1.38 g insertion.
- Inject a luteolytic dose of PGF2α 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 1.38 g removal and FTAI 16 to 20 hours later.

In non-cycling cows:
The following FTAI protocol should be used:
- Insert one CIDR 1.38 g into vagina for 9 days.
- Inject a luteolytic dose of PGF2α or analogue 24 hours prior to device removal.
- Inject eCG at CIDR 1.38 g 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 veterinary medicinal 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

For administration only by a veterinarian for the following indications:
For induction and synchronisation of oestrus in non-cycling cattle in Fixed Time Artificial Insemination (FTAI) protocols:
- To be used in combination with Gonadotrophin releasing hormone (GnRH) or analogue and PGF2α or analogue.
- To be used in combination with PGF2α or analogue and equine chorionic gonadotrophin (eCG).

3.12 Withdrawal periods

Meat and offal: zero days.
Milk: zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QG03DA04

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 30 °C.

5.4 Nature and composition of immediate packaging

Heat-sealed low-density polyethylene re-sealable sachet (zip-line).

Package size:
A sachet containing 10 devices.

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

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned. These measures should help to protect the environment.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name}
To be completed nationally.

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.
To be completed nationally.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}
To be completed nationally.

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*)