SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prid delta 1.55 g Vaginal Delivery System for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each delivery system contains:

Active substance:
1.55 g of progesterone

Excipients:

Qualitative composition of excipients and other constituents
EthylVinylAcetate
Polyamide
Plastic tail (used as removal system)

Whitish triangular device with a plastic tail.

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 œstrus cycle in cows and heifers including:
- Synchronisation of œstrus including fixed time artificial insemination (FTAI) protocols.
- Synchronisation of oestrus of donor and recipient animals for embryo transfer. To be used in combination with a prostaglandin (PGF2α or analogue)

- Induction and synchronisation of œstrus in cycling and non cycling cattle including fixed time artificial insemination (FTAI) protocols.
  - In cycling cattle. To be used in combination with prostaglandin (PGF2α) or analogue.
  - In cycling and non-cycling cattle. To be used in combination with gonadotropin 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 sexually immature heifers or females with abnormal genital tracts e.g. freemartins.
Do not use before 35 days have passed since previous calving.

Do not use in animals suffering from infectious or non-infectious disease of the genital tract.
Do not use in pregnant animals.

3.4 Special warnings

The percentage of cows displaying oestrus within a given period following treatment is usually greater than in untreated cows and the subsequent luteal phase is of normal duration. However, the progesterone treatment alone, according to dosage regimen proposed, is not sufficient to induce oestrus and ovulation in all cycling females.
In order to optimise the protocol, it is advisable to determine cycling ovarian activity before using the progesterone treatment.
Animals in poor condition, whether from illness, inadequate nutrition, under unnecessary stress or other factors, may respond poorly to treatment.

3.5 Special precautions for use

Special precautions for safe use in the target species:
It is recommended to wait a minimum of 35 days following parturition before starting the treatment with this product.

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. Do not eat or drink when handling the veterinary medicinal product.
Wash hands after use.

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

3.6 Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site inflammation[1] Vaginal discharge[1,2]

[1]Mild, local, disappearing rapidly without any treatment between removal and insemination and not affecting fertility at inseminations nor pregnancy rates.
[2]Cloudy vulvar secretions at device removal.

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 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 and lactation:
Can be used during lactation.
Do not use before 35 days have passed since previous 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.
The use of the product is contra indicated in pregnant cattle.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Vaginal use.
1.55 g of progesterone / animal for 7 days.

Judgment on the 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 could be used.

For synchronisation of oestrus (including synchronisation of oestrus of donor and recipients animal for embryo transfer)
- Insert the device for 7 days.
- Inject a prostaglandin (PGF2 α) or analogue 24 hours prior to device removal
- Removal of the device
- In animals that respond to treatment the onset of oestrus generally occurs within 1-3 days after removal of the device. 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 literature:

In cycling cattle:
- Insert the device for 7 days.
- Inject a prostaglandin (PGF2 α) or analogue 24 hours prior to device removal
- Removal of the device
- Animals should be inseminated 56 hours after removal of the device.

In cycling and non-cycling cattle (including recipient cows):
- Insert the device for 7 days.
- Inject GnRH or analogue at the device insertion.
- Inject a prostaglandin (PGF2 α) or analogue 24 hours prior to device removal
- Animals should be inseminated 56 hours after removal of the device, or
- Inject GnRH or analogue 36 hours after device removal and FTAI 16 to 20 hours later.

Or in alternative,
- Insert the device for 7 days.
- Inject GnRH or analogue at the device insertion
- At device removal inject prostaglandin (PGF2 α) or analogue

- Inject GnRH or analogue 56 hours after removal of the device
- Animals should be inseminated 16 to 20 hours later

In non-cycling cattle:
- Insert the device for 7 days.
- Inject a prostaglandin (PGF2 α) or analogue 24 hours prior to device removal
- Inject eCG at the time of the device removal
- Animals should be inseminated 56 hours after removal of the device.

Device application information:
Using an applicator, insert one device into the vagina of the animal. The intravaginal device should stay in place for 7 days.
The device is intended for single use only.

Applicator method of use and Insertion:
A device applicator should be used for administration, following the procedure described below:

1. Clean and disinfect the applicator in a non-irritant antiseptic solution before use.

2. Fold the device and load into the applicator. The end of the device tail should be outside 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 tail is free, press the handle of the applicator and pull it out, leaving the removal tail hanging from the vulva.

7. Clean and disinfect the applicator after use and before use on another animal.

Removal:
Remove 7 days after insertion by gently pulling on the removal tail. On occasions the tail 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.

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

Not applicable

3.12 Withdrawal periods

Meat and offal: zero days
Milk: zero hours

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QG03DA04.

4.2 Pharmacodynamics

Progesterone interacts with specific intranuclear receptors and binds to specific DNA sequence on the genome and then, initiates transcription of a specific set of genes which is ultimately responsible for the translation of hormonal action into physiological events. Progesterone has a negative feedback action on the hypothalamo-pituitary axis, primarily on GnRH and consequently on LH secretion. Progesterone prevents the hormonal surge from hypophysis (FSH and LH) and so suppresses oestrus and ovulation. At removal progesterone falls dramatically in 1 hour allowing follicular maturation, oestrus and ovulation in a narrow window.

4.3 Pharmacokinetics

Progesterone is rapidly absorbed by intravaginal route. Circulating progesterone is bound to proteins in blood. Progesterone binds to corticosteroid-binding globulin (CBG) and to albumin. Progesterone is accumulated in fatty tissue due to its lipophylic properties, and in tissues/organs containing progesterone receptors. Liver is the main site of progesterone metabolism. Progesterone has a half-life of 3 hours, a Cmax of 5µg/L and a Tmax of 9h. The principal route of excretion is the faeces and the secondary route is the urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Material of the primary container
Polyester/ aluminium/ polyethylene rectangular sachet.

Pack sizes
Cardboard box containing 10 sachets of 1 device
Cardboard box containing 25 sachets of 1 device
Cardboard box containing 1 applicator and 25 sachets of 1 device
Cardboard box containing 50 sachets of 1 device
Cardboard box containing 100 sachets of 1 device
Cardboard box containing 1 applicator and 50 sachets of 1 device
Polyethylene box containing 50 sachets of 1 device
Polyethylene box containing 1 applicator and 50 sachets of 1 device
Sachet containing 10 devices

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale

7. MARKETING AUTHORISATION NUMBERS

Vm 14966/5025
Vm 14966/3024

8. DATE OF FIRST AUTHORISATION

15 October 2010

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

March 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 20 April 2026