Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

PRID E 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:
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Vaginal delivery system. Whitish triangular device with a tail.

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 œstrus cycle in cows and heifers including:
- Synchronisation of œstrus in cycling cattle. To be used in combination with a prostaglandin (PGF2α).

4.3 Contraindications

Do not use in sexually immature heifers.
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. See section 4.7.

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.
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, or other factors, may respond poorly to treatment.

4.5 Special precautions for use

Special precautions for use in animals
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 medicinal product to animals
Gloves must be worn when handling the product both during insertion and removal.
Do not eat or drink when handling the product.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

During the course of the seven day treatment, the device may induce a mild local reaction (i.e. inflammation of the vaginal wall). A clinical study carried out with 319 cows and heifers has demonstrated that 25% of animals presented ropy or cloudy vulvar secretions at the device removal. This local reaction disappears rapidly without any treatment between removal and insemination and does not affect fertility at inseminations nor pregnancy rates.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

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

Using an applicator, insert one device into the vagina of the animal. The intravaginal device should stay in place for 7 days. The device has to be used in combination with a prostaglandin, injected 24 hours prior to removal of the device.

Disinfection procedure:
The applicator must be cleaned and disinfected in a non-irritating antiseptic solution before and after use and between each animal.

Applicator method of use and Insertion:
Bend the device before inserting in the applicator. Ensure the tail is in the appropriate slot.
Lightly lubricate the distal end of the applicator with an obstetrical lubricant.
Clean the animal's vulva before gently inserting the applicator in the vagina.
Once the applicator has reached the fundus of the vagina, press on the handle to release the device.
Remove the applicator gently and ensure the tail is outside the vulva.

Removal:
Remove 7 days after insertion by gently pulling on the exposed tail.

Timing of insemination:
Animals should be inseminated 56 hours after removal of the device.

The device is intended for single use only.

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

Not applicable.

4.11 Withdrawal period(s)

Meat and offal: zero days
Milk: zero days
During the treatment meat, offal and milk can be delivered for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet code: QG03DA04.

Pharmacotherapeutic group: Sex hormones (progestogens).

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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 $C_{max}$of 5 µg/L and a $T_{max}$of 9 hours. The principal route of excretion is the faeces and the secondary route is the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

EthylVinylAcetate
Polyamide
Plastic tail

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life of the veterinary medicinal product after first opening the sachet of 10 devices: 6 months.

6.4 Special precautions for storage

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

6.5 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 1 applicator and 50 sachets of 1 device
Cardboard box containing 100 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

LAPROVET
7, rue du Tertreau
Arche d'Oé 2
37390 Notre Dame d'Oé
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10483/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of 1st authorisation: 24th August 2012

10 DATE OF REVISION OF THE TEXT

January 2018