

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

PRID 1.55 g progesterone releasing intra-vaginal device.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each spiral device contains:

Active substance

Progesterone 1.55 g

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Vaginal delivery system.

A spiral device covered with an inert elastomer containing progesterone.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (cows and heifers).

4.2 Indications for use, specifying the target species

Synchronisation of oestrus in groups of cycling cows and sexually mature heifers. To be used in combination with a prostaglandin.

Management:

Planned breeding: by synchronising ovarian activity, PRID enables beef cows, dairy cows and heifers to be inseminated at a predetermined fixed time without the need for oestrus detection, thus reducing the calving index and the number of cows culled.

4.3 Contraindications

Do not use in sexually immature heifers.

Do not use in females with abnormal genital tracts e.g. freemartins.

Do not use in animals with genital infections or vaginal discharge.

Do not use in cows and heifers in a poor nutritional state.

4.4 Special warnings for each target species

Adequate nutrition is required to obtain good fertility results.

Avoid any stress around the treatment period (e.g. sudden dietary changes, vaccination, branding etc.)

Animals should show no discomfort following insertion. In the event of an animal continuing to strain after insertion, remove the device and serve at the next oestrus.

It is recommended to wait a minimum of 35 days following parturition before starting treatment with this product. Prostaglandins are contraindicated in pregnancy.

4.5 Special precautions for use

Special precautions for use in animals

Do not damage the device when loading the speculum. If device is damaged, discard and replace with a fresh device. If a damaged device is inserted by accident, there is a risk that traces of blood may occur following withdrawal of the device. Insertion into the vagina of normal cows and heifers should present no difficulty. If insertion is difficult, the device should not be used.

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

Gloves must be worn when handling the product both during insertion and at removal.

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

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

A vaginal discharge commonly occurs, this clears spontaneously without treatment after the device is removed and has no effect on fertility.

4.7 Use during pregnancy, lactation or lay

The product can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

1.55 g of progesterone / animal for 7 days.

Using a speculum, or PRID Gun-type or Quick-fit Applicator, insert one device into the vagina of each cow or heifer to be inseminated. See insertion guidelines below. Take care not to damage the device; handle gently, especially during insertion.

The device should be inserted intra-vaginally and remain in place for 7 days.

A prostaglandin (PGF2 α) should be administered by injection, according to the dose recommendations of the chosen product, 24 hours before the removal of the device.

Disinfection procedure:

Before each application, the applicator must be cleaned and disinfected according to the recommendations supplied.

Insertion: Set the product on the applicator and lubricate the lip of the applicator inside and outside with a disinfectant cream. The use of obstetrical lubricants may increase the loss rate.

Clean the vulva immediately prior to insertion using a suitable paper wipe. Holding the applicator in one hand, spread the lips of the vulva with the other and gently insert the applicator into the vagina. Then gently push it into the interior vaginal area, until it reaches the cervix.

Release the device from the applicator into the vagina. Leave the device string extended out of the vulva. String length should not exceed 10 cm. If necessary, adjust by cutting off the end.

Disinfect the applicator in accordance with the directions.

Removal:

The device is intended for single use only.

Remove 7 days after insertion by gently pulling the exposed string. If the string is not visible, the device may still be present. Insert a clean, gloved hand into the vagina and retract the device. This may be facilitated by using one hand in the rectum to move the coil towards the vulva. Occasionally a coil will be expelled by the animal.

Retention rates should be in the order of 98%. However, it may be lower in multiparous and large cows. Consequently there may be an advantage in enlarging the device before manual insertion (see package leaflet for further details). This is not possible with PRID 'Quickfit'.

Timing of insemination:

It is recommended that animals are inseminated twice at 48 and 72 hours after removal of the device. If more practicable, animals may be inseminated only once 56 hours after removal.

Animals which lose the coil during the 7-day treatment period should be inseminated/served at the next observed oestrus.

Animals in normal oestrus more than 24 hours after the last insemination should be reinseminated normally. In herds where oestrus detection is impractical and pedigree registration of the calf is not required, a bull may be introduced 24 hours after fixed time AI.

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

Possible effects if the device stays in the vagina more than 12 days were not assessed.

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 is a naturally occurring steroid produced by the corpus luteum. Progesterone interacts with specific intranuclear receptors and binds to specific DNA sequence on the genome. Progesterone subsequently 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 LH secretion. Progesterone prevents the hormonal surge from hypophysis (FSH and LH) and so suppresses oestrus and ovulation. When the device is removed, the drop in progesterone concentrations induces a new oestrus cycle in treated animals.

5.2 Pharmacokinetic properties

Progesterone is rapidly absorbed by intravaginal route. While the device is in place, milk and blood progesterone levels are within the normal range seen in untreated cows during the luteal phase of a normal oestrous cycle. The released progesterone undergoes the same bio-transformation as endogenous progesterone. 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 lipophilic properties, and in tissues/organs containing progesterone receptors. The liver is the main site of progesterone metabolism. Progesterone has a half-life of 3 hours, a Cmax of 5 µg/L and a Tmax of 9h. The principal route of excretion is the faeces and the secondary route is the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Elastomer silicone
Dimeticone
Polyester cord
Stannous octoate
Support treated stainless steel strip

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 4 years

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

A progesterone releasing intravaginal device. Devices are packed individually in polyethylene bags for use with the original PRID speculum or are pre-rolled onto a plastic cartridge for use with the “Quick fit” applicator. These are then packed 6 or 10 devices per carton.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Ceva Animal Health Limited
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10995/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2007

10 DATE OF REVISION OF THE TEXT

10th November 2011