

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Eazi-Breed CIDR Cattle Device.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each device contains:

Active Substance

Progesterone	1.94 g
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For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Vaginal delivery system.

4 CLINICAL PARTICULARS

4.1 Target Species

Bovine (Cows and Heifers)

4.2 Indications for use, specifying the target species

The EAZI-BREED CIDR Cattle device is used to provide a cow or heifer with an exogenous source of the natural hormone progesterone.

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

synchronisation of oestrus in groups of animals

synchronisation of donor and recipient animals for embryo transfer.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

None.

4.6 Adverse reactions (frequency and seriousness)

Signs of local irritation are rare, but a vaginal discharge may occasionally occur. This should resolve spontaneously after removal of the device.

4.7 Use during pregnancy, lactation or lay

This product is not intended for use during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

One EAZI-BREED CIDR Cattle device should be inserted into the vagina of each cow or heifer to be treated. The device should be left in position for between 7 and 12 days with an injection of a luteolytic dose of prostaglandin F2 α or analogue either at the time of device removal, or at any time from 6 days after insertion.

The above normally results in oestrus 48 to 96 hours after EAZI-BREED CIDR Cattle device removal, with the majority of animals showing oestrus within 48 to 72 hours. Mating or insemination to observed oestrus is advised, and the use of heat detection aids such as tail paint is recommended.

ADMINISTRATION

An Eazi-Breed CIDR Cattle Device applicator should be used for administration, following the procedure described below:

1. Ensure that the applicator is clean and dip in a non-irritant antiseptic solution. If required, to ease application, the end of the applicator may be dipped in obsterical libricant prior to use.
2. wearing plastic gloves, fold the wings of an Eazi-Breed CIDR Cattle device and load into applicator. The wings of the device should protrude slightly from the end of the applicator.
3. Apply a small quantity of obsterical 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 resistance is encountered.
6. Make sure the removal tail is free, press the handle of the applicator and allow the barrel to move back towards the handle. This releases the wings of the device, which will then retain it in the anterior vagina.
7. With the Eazi-Breed CIDR Cattle Device correctly positioned withdraw the applicator, leaving the removal tag hanging from the vulva.
8. The applicator should be cleaned and disinfected before being used on another animal.

REMOVAL

The Eazi-Breed CIDR Cattle Device may be removed by gently pulling on the removal tag. On occasions the tail of the device 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.

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

Not applicable.

4.11 Withdrawal Period(s)

Animals intended for human consumption may only be slaughtered from 6 hours from removal of the device.
Milk: Nil. Milk for human consumption may be taken from lactating cows during treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Progesterone release from the EAZI-BREED CIDR Cattle device is designed to maintain plasma progesterone concentration at a sufficient level to inhibit release of the pituitary gonadotrophins FSH and LH and so prevent the onset of oestrus. Provided no endogenous source of progesterone exists, removal of the device will result in a sudden fall in plasma progesterone. This will normally trigger release of FSH and LH and the onset of oestrus at a predictable time.

5.2 Pharmacokinetic properties

Pharmacokinetics:

The EAZI-BREED CIDR Cattle device delivers progesterone at a controlled rate across the vaginal mucosa into the blood stream. The amount of progesterone is sufficient to inhibit follicle maturation and so control the oestrus cycle. After removal of the device, circulating blood levels of progesterone fall precipitously within 6 hours, allowing follicle maturation, behavioural oestrus and ovulation.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Silicone Elastomer
Polyamide Spine

6.2 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 25°C.

6.5 Nature and composition of immediate packaging

The EAZI-BREED CIDR devices are packed in heat-sealed laminated sachets composed of paper (Outside), polythene, aluminium foil, and polyethylene (inside).

Packs: 5 x 10 devices.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Pfizer Healthcare Ireland,
Ringaskiddy,
Co. Cork,
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10019/109/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

7th March 2005

10 DATE OF REVISION OF THE TEXT

13th July 2007