SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EAZI BREED CIDR G VETERINARY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances(s):
Each device contains:
Progesterone 0.35 g

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Vaginal delivery system.
A “T” shape device consisting of progesterone impregnated silicone rubber elastomer skin moulded over an inert nylon spine.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep (ewes).

4.2 Indications for use, specifying the target species

Estrus control in sheep.

4.3 Contraindications

Do not use in pregnant ewes.
Do not use in ewes:
- with abnormal or immature genital tracts.
- with genital infections.

4.4 Special warnings

None.

4.5 Special precautions for use

i) Special precautions for use in animals

The efficacy and safety of the veterinary medicinal product has not been evaluated in ewes which are unwell, which have a BCS < 2 or ≥ 4, which have had complications during previous pregnancies or lambings, or which have lambed within the last 45 days. Use only according to the benefit/risk assessment by the responsible veterinarian.
Animals in poor condition, whether from illness, inadequate nutrition, or other factors, may respond poorly to treatment.

ii) 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.
Adverse effects on unborn children cannot be ruled out.
The product may cause skin and eye irritation, as well as allergic skin rashes.
Those administering the product should avoid contact with the silicone section; pregnant women should avoid using the product completely.
Wear gloves when administering and disposing of the product; insert the device using the applicator.
Wash hands and exposed skin with soap and water after use.
Do not smoke, eat or drink while handling the product.

4.6 Adverse reactions (frequency and seriousness)

Local irritation and discharge of cloudy/yellow mucus are common and discharge of dark red/brown mucus or mucus with fresh blood is uncommon. However, these signs typically resolve within 2 days of removal of the device without the need for treatment.
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to theNational Regulation by using an online form https://sideeffects.health.gov.il/.

4.7 Use during pregnancy, lactation or lay

See section 4.3. The safety of the veterinary medicinal product has not been established during lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For induction of estrus in ewes (sheep) during seasonal anestrus:
• Administer one EAZI-BREED CIDR Sheep Insert per ewe for 5 days.
• After insert removal, use standard flock breeding procedures to breed ewes at induced estrus.

Insertion:

1. Avoid contact with skin by wearing protective gloves when handling inserts.
2. Only use the specially designed EAZI-BREED CIDR Sheep Insert Applicator for administration.
3. Restrain ewes appropriately prior to administration.
4. Wash the applicator in a non-irritating antiseptic solution, and then apply a veterinary obstetrical lubricant to the end of the applicator.

5. Push the tail end of the EAZI-BREED CIDR Sheep Insert into the applicator taking care to assure the tail is extending upward through the slot of the applicator and is pointed away from the handle.
6. Fold the wings of the EAZI-BREED CIDR Sheep Insert to make it longer and continue to advance the insert into the applicator until it is fully seated with only the tips of the wings protruding from the end of the applicator (see Figure 1).
7. Lubricate the protruding tips of the wings of the EAZI-BREED CIDR Sheep Insert with veterinary obstetrical lubricant.
8. Clean the exterior of the vulva with disposable tissue.
9. Open the lips of the vulva and gently place the loaded applicator through the vulva. The slot in the applicator should face down (see Figure 2).
10. Once the loaded applicator is past the vulva slope the applicator slightly upwards (35 - 45° angle) by lowering the handle, and then forward, without forcing, until the applicator is fully inserted or resistance is felt (see Figure 3).
11. Squeeze the finger grips within the handle of the applicator to deposit the EAZI-BREED CIDR Sheep Insert in the anterior vagina (see Figure 4) and then pull the applicator backwards to remove it from the vagina.
12. With the EAZI-BREED CIDR Sheep Insert correctly placed, with the wings open in the anterior portion of the vagina, the tail of the insert should be visible, pointing downward from the vulva of the ewe.

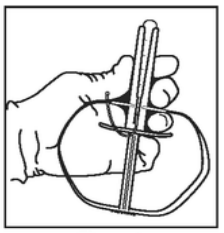

Figure 1

Figure 2

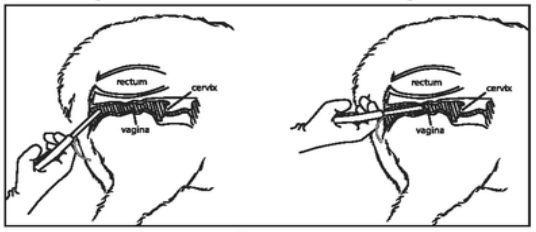

Figure 3

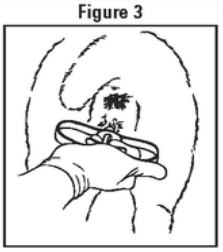

Figure 4

Removal:

1. Remove EAZI-BREED CIDR Sheep Inserts by pulling, gently but firmly, on the protruding nylon tail.
2. EAZI-BREED CIDR Sheep Inserts may reverse direction within the vagina; therefore, if the nylon tail of the insert is not visible on the day of removal, check the vagina to determine if an insert is present.
3. Used (removed) EAZI-BREED CIDR Sheep Inserts must be stored in a sealable container until disposed. Sealed bag/container with used EAZI-BREED CIDR Sheep Inserts must be properly disposed in accordance with applicable local, state and Federal regulations.

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 hours.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Genito Urinary System and Sex Hormones
ATCVet code: QG03DA04

5.1 Pharmacodynamic properties

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, allowing follicle maturation, behavioural oestrus and ovulation.

5.2 Pharmacokinetic particulars

The pharmacokinetic profile of progesterone when administered as a single device was characterised by a maximum concentration (Cmax) in plasma of up to 5.9 ng/mL achieved post-dosing. Peak concentrations were followed by a decline in systemic exposure to a steady state of approximately 2 ng/mL. After removal of the device, circulating blood levels of progesterone fall precipitously within 2-4 hours reaching baseline levels by 12 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid silicon rubber
Nylon Spine

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials. The expiry date refers to the last day of that month.

6.4 Special precautions for storage

Do not store above 25° C.

6.5 Nature and composition of immediate packaging

The devices are packed in heat-sealed low-density polyethylene sachets in units of 20 per sachet.

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

Any unused veterinary medicinal product or waste materials from such veterinary medicinal products should be disposed of as a toxic waste. Do not dispose of in the sewage system.

7. MARKETING AUTHORISATION HOLDER

Zoetis Israel Holding B.V. 5 Atir Yeda Street, Kfar Saba, Israel

8. MARKETING AUTHORISATION NUMBER

083-62-91947-00

9. MANUFACTURER

DEC International, New Zealand Ltd., 558 Te Rapa Rd. Hamilton, New Zealand

10. DATE OF REVISION OF THE TEXT

Revised in December 2021 according to MOHs guidelines