SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CIDR OVIS 0.35 g Vaginal Delivery System for Sheep

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

For the induction and synchronization of oestrus and ovulation in non-cycling ewes during seasonal anoestrus.
For the induction and synchronization of oestrus and ovulation in cycling and in non-cycling ewes for advancing the breeding season.
To be used in combination with eCG.

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.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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

0.35 g of progesterone per animal for 12 days.

One device should be inserted into the vagina of each ewe to be treated. The vaginal insert should be left in position for 12 days followed by an injection of equine Chorionic Gonadotrophin (eCG, formerly known as PMSG) administered at device removal. The onset of oestrus occurs within 1-2 days after removal of the insert.

In a study of 11 Lacaune breed ewes, ovulation occurred between 42 and 58 hours following eCG injection, with the majority (73%) ovulating between 50 and 54 hours. In the case that artificial insemination and advanced breeding techniques (e.g. embryo

transfer) are applied, the timing of ovulation should be taken into consideration for the selected technique for optimal results.

Administration
A device applicator should be used for administration, following the procedure described below:

1. Ensure that the applicator is clean and dipped in a non-irritant antiseptic solution before use.
2. Wearing sterile disposable plastic gloves, fold the arms of the device and load into the applicator. The arms of the device should protrude slightly from the end 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 string is free, press the handle of the applicator and allow the barrel to move back towards the handle. This releases the arms of the device, which will then retain the device in the anterior vagina.
7. With the device correctly positioned, withdraw the applicator, leaving the removal string exiting from the vulva.

The applicator should be cleaned and disinfected before being used on another animal.

Removal
The device may be removed by gently pulling on the tail. 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. Approximately 1 in 10 devices may be lost by an animal. Withdrawal of the device should not require force. If any resistance is encountered a gloved finger 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.

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

Silicone elastomer
Nylon spine

6.2 Incompatibilities

Not applicable.

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 30° 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 derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
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Surrey
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8. MARKETING AUTHORISATION NUMBER

Vm 42058/4206

9. DATE OF FIRST AUTHORISATION

27 July 2017

10. DATE OF REVISION OF THE TEXT

November 2019

Approved: 12 November 2019