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

Each device contains:

Active substances:

Progesterone 0.35 g

Excipients:

Qualitative composition of excipients and other constituents
Silicone elastomer
Nylon spine

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

3. CLINICAL INFORMATION

3.1 Target species

Sheep (ewes).

3.2 Indications for use for each 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 (equine chorionic gonadotrophin).

3.3 Contraindications

Do not use in sexually immature ewes or in females with abnormal genital tracts.
Do not use in animals presenting with infectious or non-infectious diseases of the genital tract.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
See section 3.7

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

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.
As adverse effects on unborn children cannot be ruled out, pregnant women should avoid using this veterinary medicinal product.
The veterinary medicinal product may cause skin and eye irritation, as well as allergic skin rashes. Avoid accidental contact with the eyes. In case of accidental ocular exposure, flush the eyes thoroughly with water.

Persons administering the veterinary medicinal product should avoid contact with the silicone section; pregnant women should avoid using the veterinary medicinal product.

The device should be inserted using the product specific applicator. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product during insertion and removal.

Wash hands and exposed skin with soap and water after use.
Do not smoke, eat or drink while handling the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Sheep:

Common (1 to 10 animals / 100 animals treated):	Application site irritation[1], vaginal discharge[1] (cloudy/yellow mucus)
Uncommon (1 to 10 animals / 1,000 animals treated):	Vaginal discharge[1] (dark red/brown mucus with fresh blood)

[1] typically resolve within 2 days of removal of the device without the need for treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also section 'Contact details' of the package leaflet.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Do not use in pregnant ewes.
The safety of the veterinary medicinal product has not been established during lactation. During lactation use only according to the benefit/risk assessment by the responsible veterinarian.

3.8 Interactions with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Vaginal use.
0.35 g of progesterone (1 device) 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 veterinary medicinal 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: zero days.
Milk: zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QG03DA04

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

The pharmacokinetic profile of progesterone when administered as a single device was characterised by a maximum concentration (C_{max}) 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

Do not store above 30 °C.

5.4 Nature and composition of immediate packaging

Heat-sealed low-density polyethylene sachets.
Package size:
A sachet containing 20 devices.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

7. MARKETING AUTHORISATION NUMBER

Vm 42058/3018

8. DATE OF FIRST AUTHORISATION

27 July 2017.

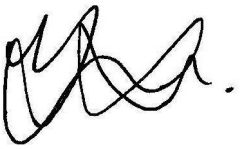
9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

October 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).



Approved: 04 April 2024