LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Facing page of Booklet Label (bag 20 devices)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CIDR OVIS 0.35 g Vaginal Delivery System for Sheep
Progesterone

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each device contains progesterone 0.35 g.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 devices

4. ROUTE(S) OF ADMINISTRATION

Vaginal use.

5. WITHDRAWAL PERIOD

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

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

<EXP {month/year}>

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Label face physically stuck to the bag (20 devices)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CIDR OVIS 0.35 g Vaginal Delivery System for Sheep
Progesterone

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each device contains progesterone 0.35 g.

3. PHARMACEUTICAL FORM

Vaginal delivery system.

4. PACKAGE SIZE

20 devices

5. TARGET SPECIES

Sheep

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTES OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 30ºC

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis subsidiaries in the concerned European Union Member States

16. MARKETING AUTHORISATION NUMBER(S)

TBA

17. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

CIDR OVIS 0.35 g Vaginal Delivery System for Sheep

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
To be completed nationally

Manufacturer responsible for batch release:
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CIDR OVIS 0.35 g Vaginal Delivery System for Sheep
Progesterone

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each device contains progesterone 0.35 g in a silicone rubber elastomer skin moulded over an inert “T” shape nylon spine.

4. INDICATIONS

For the induction and synchronisation 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.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Sheep (ewes)

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Vaginal use.
0.35 g of progesterone per animal. The vaginal insert should be left in position for 12 days followed by an injection of eCG (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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 30°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

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.
Do not use in pregnant ewes. 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.'

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.

Pregnancy:

The safety of the veterinary medicinal product has not been established in pregnant ewes and the use is not recommended during gestation

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
Not applicable.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

TBC

15. OTHER INFORMATION

For animal treatment only.
Sachet of 20 devices