ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Luteoplan 0.25 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Cloprostenol 0.25 mg/ml as cloprostenol sodium.

3. PACKAGE SIZE

20 ml.

4. TARGET SPECIES

Cattle (heifers and cows) and horses (mares).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle
Meat and offal: 1 day.
Milk: Zero days.

Horses
Meat and offal: 4 days.
Milk: 24 hours.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special temperature storage conditions.
This veterinary medicinal product should be stored upright.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Syn Vet-Pharma Ireland Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 54400/3000

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20 ML VIAL LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Luteoplan

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

0.25 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Luteoplan 0.25 mg/ml solution for injection for cattle and horses.

2. Composition

Each ml contains:

Active substance:
Cloprostenol 0.25 mg (as 0.263 mg Cloprostenol Sodium)

Excipients:
Chlorocresol 1.0 mg

Clear, colourless solution.

3. Target species

Cattle (heifers and cows), and horses (mares).

4. Indications for use

Cattle (heifers, cows):
- Synchronisation or induction of oestrus;
- Treatment of ovarian dysfunction (persistent corpus luteum, luteal cyst);
- Treatment of uterine disorders related to a functioning or persistent corpus luteum (endometritis, pyometra);
- Induction of abortion until day 150 of pregnancy;
- Expulsion of mummified foetuses;
- Induction of parturition.

Horses (mares):
Induction of luteolysis with a functional corpus luteum.

5. Contraindications

Do not use in pregnant animals unless the objective is to induce parturition or abortion.
Do not use in animals with cardiovascular, gastro-intestinal or respiratory problems.
Do not administer to induce parturition in cattle with suspected dystocia due to mechanical obstruction or if problems are expected because of an abnormal position of the foetus.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer intravenously.

6. Special warnings

Special precautions for safe use in the target species:

There is a refractory period of four to five days after ovulation when cattle and horses are insensitive to the luteolytic effect of prostaglandins.

Cattle:

For the induction of abortion, best results are obtained before day 100 of gestation. Results are less reliable between day 100 and 150 of gestation.
In case of oestrus induction in cattle: from the 2nd day after injection, adequate heat detection is necessary.

Induction of parturition and abortion may increase the risk of complications, retained placenta, foetal death and metritis.
To reduce the risk of anaerobic infections (e.g. swelling, crepitus), which might be related to the pharmacological properties of prostaglandins, care should be taken to avoid injection through contaminated areas of skin. Clean and disinfect injection sites thoroughly before administration.
All animals should receive adequate supervision after treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Prostaglandins of the F2α type, such as cloprostenol, can be absorbed through the skin and may cause bronchospasm or miscarriage.
Care should be taken when handling the veterinary medicinal product to avoid self-injection or skin contact.
Pregnant women, women of child-bearing age, asthmatics and people with bronchial or other respiratory problems should avoid any contact with the veterinary medicinal product.
Wear disposable impervious gloves when administering the veterinary medicinal product.
Accidental spillage on the skin should be washed off immediately with soap and water.
If accidental contact with eyes occurs, rinse the affected eyes thoroughly with clean, fresh water.
In case of accidental self-injection or spillage onto the skin, seek medical advice immediately, particularly as shortness of breath may occur, and show the package leaflet or label to the physician.
Do not eat, drink or smoke while handling the veterinary medicinal product.
Chlorocresol may cause irritation and allergic reactions. People with known hypersensitivity to chlorocresol should administer the veterinary medicinal product with caution.

Pregnancy and lactation:

Do not administer to pregnant animals unless the objective is to induce parturition or abortion.
The veterinary medicinal product can be used safely during lactation.

Interaction with other medicinal products and other forms of interaction:

Do not administer the veterinary medicinal product together with non-steroidal anti-inflammatory drugs since they inhibit endogenous prostaglandin synthesis.
The activity of other oxytocic agents can be increased after the administration of cloprostenol.

Overdose:

Overdose may be associated with uneasiness and diarrhoea. These effects are usually transient and will resolve without treatment.

In mares, if the indicated dosage is exceeded, clinical signs such as sweating, diarrhoea, dyspnoea, tachycardia, colic can occasionally be observed.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

In cattle:

Rare (1 to 10 animals / 10,000 animals treated): Injection site infection (which may become generalised)*1
Very rare (<1 animal / 10,000 animals treated, including isolated reports): Anaphylaxis*2
Undetermined frequency Dystocia, foetal death, retained placenta and/or metritis*3

*1 Typical local reactions due to anaerobic infection are swelling and crepitus at the injection site.
*2 Anaphylactic reactions require immediate medical attention.
*3 These adverse events may be observed when used in cattle for induction of parturition or abortion, dependent on the time of treatment relative to the date of conception.

In horses:

Rare(1 to 10 animals / 10,000 animals treated): Injection site infection (which may become generalised)[*1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports): Anaphylaxis[*2]
Undetermined frequency Increased sweating[*3], incoordination, muscle tremors[*3], increased heart rate, increased respiratory rate, abdominal discomfort, loose stool[*4], lying down.

[*1] Typical local reactions due to anaerobic infection are swelling and crepitus at the injection site.
[*2] Anaphylactic reactions require immediate medical attention.
*[3] Mild sweating and muscle tremors that may occur after treatment appear to be transient and resolve without any treatment.
[*4] Loose stool may be passed shortly after treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Intramuscular use.

Cattle:
0.5 mg cloprostenol/animal corresponding to 2 ml of the veterinary medicinal product per animal.
Induction of oestrus: Administer one dose of the veterinary medicinal product after determination of the presence of a functional corpus luteum (6th to 18th day of cycle). Heat usually appears within 2 to 5 days. Proceed to insemination 72 to 96 hours after treatment. If there is no sign of oestrus, the treatment may be repeated 11 days after the first injection.

Synchronisation of oestrus: Administer one dose of the veterinary medicinal product on two occasions with an 11 day interval between treatments. Proceed with insemination 72 to 96 hours after the second injection.

Treatment of ovarian dysfunction (persistent corpus luteum, luteal cyst): Administer one dose of the veterinary medicinal product after determination of presence of the corpus luteum. Then, proceed to inseminate at the first oestrus after injection. If oestrus does not take place, conduct a further gynaecological examination, and repeat the injection 11 days after the first administration.

Treatment of uterine disorders (clinical endometritis, pyometra): Administer one dose of the veterinary medicinal product preferably before the 60th day post-partum. If necessary, repeat the treatment at the latest after 10-11 days.

Induction of abortion: Administer one dose of the veterinary medicinal product until day 150 after insemination.

Expulsion of mummified foetuses: Administer one dose of the veterinary medicinal product.

Induction of parturition: Administer the veterinary medicinal product within 10 days before the expected date of parturition. Birth usually occurs within 30-60 hours of treatment.

Horses:
Ponies: administer 0.125 to 0.250 mg cloprostenol/animal corresponding to 0.5 to 1 ml of the veterinary medicinal product per animal.
Light horses: 0.250 mg cloprostenol/animal corresponding to 1 ml of the veterinary medicinal product per animal.
Heavy horses: 0.500 mg cloprostenol/animal corresponding to 2 ml of the veterinary medicinal product per animal.

9. Advice on correct administration

It is recommended that the vial is not broached more than 10 times.

Do not use the veterinary medicinal product if you notice particulates or cloudiness of solution.

10. Withdrawal periods

Cattle
Meat and offal: 1 day.
Milk: Zero days.

Horses and ponies
Meat and offal: 4 days.
Milk: 24 hours.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special temperature storage conditions.
This veterinary medicinal product should be stored upright.

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.

Shelf life after first opening the container: 28 days

When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the carton.

12. Special precautions for disposal

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

The veterinary medicinal product should not enter water courses as cloprostenol may be dangerous for fish and other aquatic organisms.

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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

20 ml glass vial in cardboard box.

Vm 54400/3000

15. Date on which the package leaflet was last revised

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

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

16. Contact details

Marketing authorisation holder:
Syn Vet-Pharma Ireland Limited
7 A Durands Court
45 Parnell Street
Waterford – X91 P381
Ireland

Manufacturer responsible for batch release:
V.M.D. NV
Hoge Mauw 900
2370 Arendonk
Belgium

<Local representatives <and contact details to report suspected adverse reactions>:>

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

United Kingdom (Northern Ireland)
{Name}
<{Address}
{Town} {Postal code} – UK>
Tel: + {Telephone number}
<{E-mail}>>

Approved 18 October 2023