ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

INDUPART 75 micrograms /mL solution for injection
D-cloprostenol (sodium) **[AT / BG / CZ / DE / ES / HU / LT / LV / PT / SK / RO / BE / IE / LU / NL]**

INDUPART [**DK]**

GANAPAR 75 micrograms /mL solution **[PL / EE]**
D-cloprostenol (sodium)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
D-Cloprostenol (as D-cloprostenol sodium) ..... 75 micrograms

3. PACKAGE SIZE

20 ml
5 x 20 ml

4. TARGET SPECIES

Cattle (cows), pigs (sows) and horses (mares).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:	Meat and offal:	Zero days
	Milk:	Zero hours
Pigs:	Meat and offal:	1 day
Horses:	Meat and offal:	2 days
	Milk:	Zero hours

8. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days.

Once opened, use by…

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.

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

VETPHARMA ANIMAL HEALTH, S.L.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

INDUPART 75 micrograms /mL solution for injection
[AT / BG / CZ / DE / ES / HU / LT / LV / PT / SK / RO / BE / IE / LU / NL]

INDUPART [**DK]**

GANAPAR 75 micrograms /mL solution for injection **[PL / EE]**

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

D-cloprostenol (sodium) 75 µg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {month/year}

Once opened use within 28 days.
Once opened, use by…

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

INDUPART 75 micrograms /mL solution for injection for cattle, pigs and horses
D-cloprostenol (sodium) [**AT / BG / CZ / DE / ES / HU / LU / LT / LV / PT / SK / RO / BE / IE / LU / NL]**

INDUPART [**DK]**

GANAPAR 75 micrograms /mL solution for injection for cattle, pigs and horses
D-cloprostenol (sodium) **[PL, EE]**

2. Composition

Each ml contains:

Active substance:
D-cloprostenol (as D-cloprostenol sodium)..... 75 micrograms

Excipients:

Chlorocresol..... 1.0 mg

Clear colourless solution

3. Target species

Cattle (cows), pigs (sows) and horses (mares).

4. Indications for use

Cattle:
- Synchronisation or induction of oestrus;
- Induction of parturition;
- Ovarian dysfunction (persistent *corpus luteum*, luteal cyst);
- Endometritis, pyometra;
- Delayed uterine involution;
- Induction of abortion in the first half of pregnancy;
- Expulsion of mummified foetuses;

Pigs:
Induction of parturition.

Horses:
Induction of luteolysis in mares with a functional *corpus luteum.*

5. Contraindications

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

6. Special warnings

Special precautions for safe use in the target species:
- Induction of parturition and abortion may increase the risk of complications, retained placenta, foetal death and metritis.
- To reduce the risk of anaerobic infections, 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.
- In case of oestrus induction in cows: from the 2nd day after injection, adequate heat detection is necessary.
- Induction of parturition in sows before day 114 of gestation may result in an increased risk of stillbirths and the need for manual assistance at farrowing.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
d-Cloprostenol, like all $F_{2\alpha}$ prostaglandins, can be absorbed through the skin and can produce bronchospasm and abortion.
Direct contact with skin or mucous membranes of the user should be avoided. Pregnant women, women of child-bearing age, asthmatics and persons with bronchial problems or any other type of respiratory problem must avoid any contact or use disposable plastic gloves when administering the veterinary medicinal product.

The veterinary medicinal product must be handled carefully to avoid accidental self-injection or skin contact.
In case of accidental self injection seek medical advice immediately and show the package leaflet or the label to the physician.
Seek medical advice immediately in case of any respiratory difficulty caused by accidental inhalation or inoculation.
In case of accidental skin contact, wash with soap and water immediately.
Do not eat, drink or smoke while handling the veterinary medicinal product.

Pregnancy:
Do not use (during the whole or part of the pregnancy) unless it is desirable to induce parturition or therapeutic interruption of pregnancy as the use in gestating animals produces abortion.

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:
At 10 times the therapeutic dose, no adverse reactions were reported in cows and sows. In general, a large overdose could result in the following symptoms: increased pulse and breathing rate, bronchoconstriction, increased body temperature, increased amounts of loose faeces and urine, salivation and vomiting. As no specific antidote has been identified, in the case of overdose, symptomatic therapy is advisable. An overdose will not accelerate corpus luteum regression.

In mares, moderate sweating and soft faeces was detected when administered 3 times the therapeutic dose.

Special restrictions for use and special conditions for use

Not applicable.

[ES]: Administration under the control or direct responsibility of a veterinary surgeon.

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

7. Adverse events

Cows:

Undetermined frequency (cannot be estimated from the available data):
Injection site infection (injection site swelling, crepitus)[1] Retained placenta [2]

[1]. If anaerobic bacteria penetrate the tissue of the injection site.
[2]. The incidence may be increased when used in cows for induction parturition and dependent on the time of treatment relative to the date of conception

Sows:

Undetermined frequency (cannot be estimated from the available data):
Behavioural changes[1]

[1.] Similar to those changes associated with natural farrowing and usually cease within one hour.

Horses:

None known

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 or the local representative of 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.

Cows: Administer 2 ml of the veterinary medicinal product/animal, equivalent to 150 µg of d-cloprostenol/animal:

- Synchronisation of oestrus: administer the veterinary medicinal product twice, with an interval of 11 days between each dose. Proceed therefore with two artificial inseminations at intervals of 72 and 96 hours from the second injection.
- Induction of oestrus (also in cows showing weak or silent heat): administer veterinary medicinal product after having established the presence of a corpus luteum (6-18th day of the

cycle); heat usually appears within 48-60 hours. Proceed, therefore, with insemination 72-96 hours after injection. If oestrus is not evident, administration of the veterinary medicinal product needs to be repeated 11 days after the first injection.

- Induction of parturition after day 270 of gestation: administer the veterinary medicinal product after 270 days of pregnancy. Parturition usually results within 30-60 hours of treatment.
- Ovarian dysfunction (persistent *corpus luteum*, luteal cyst): when the presence of the corpus luteum is determined administer the veterinary medicinal product, then proceed to inseminate at the first oestrus after injection. If oestrus is not evident, conduct a further gynaecological examination, and repeat the injection 11 days after the first administration. Insemination must always be carried out 72-96 hours after injection.
- Endometritis, pyometra: administer 1 dose of the veterinary medicinal product. If necessary repeat the treatment after 10 days.
- Induction of abortion in the first half of pregnancy (until day 150 of pregnancy): administer veterinary medicinal product in the first half of pregnancy.
- Expulsion of mummified foetus: administer 1 dose of the veterinary medicinal product. Expulsion of the foetus is observed within 3-4 days after administration of the veterinary medicinal product.
- Delayed uterine involution: administer veterinary medicinal product and, if considered necessary, carry out one or two successive treatments at 24 hour intervals.

Sows: Administer 1 ml of the veterinary medicinal product/animal equivalent to 75 micrograms of d-cloprostenol/animal, by intramuscular route, not earlier than 114 days of pregnancy. Repeat after 6 hours. Alternatively, 20 hours after the initial dose, a myometrial stimulant (oxytocin or carazolol) may be administered.
Following the protocol of the double administration, approximately 70-80% of the animals will give birth during the interval between 20 and 30 hours after the first administration.

Mares: Induction of luteolysis in mares with a functional *corpus luteum:* Administer 1 ml of the veterinary medicinal product/animal, equivalent to 75 µg of d-cloprostenol/animal.

9. Advice on correct administration

10. Withdrawal periods

Cattle:	Meat and offal: Zero days Milk: Zero hours
Pigs:	Meat and offal: 1 day
Horses:	Meat and offal: 2 days Milk: Zero hours

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the vial in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging : 28 days.

12. Special precautions for disposal

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

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:
Carton box with 1 vial of 20 ml.
Carton box with 5 vials of 20 ml.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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:
VETPHARMA ANIMAL HEALTH, S.L.
C/ Les Corts, 23
08028 Barcelona
Spain

Manufacturer responsible for batch release:
MEVET S.A.U.
Polígono Industrial El Segre, p. 409-410,
25191 Lérida
Spain

Local representative 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.

17. Other information