PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

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 / LT / LV / PT / SK / RO / BE / IE / LU / NL]**

INDUPART [**DK]**

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

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

20 ml vial
Box with 5 vials of 20 ml

5. TARGET SPECIES

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

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE OF ADMINISTRATION

For intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Prostaglandins can cause severe adverse reactions. See package leaflet for full user warnings.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

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

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.
To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

INDUPART 75 mcg/mL solution for injection for cattle, pigs and horses
D-cloprostenol (sodium) [**IE]**

INDUPART [**DK]**

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

D-cloprostenol (sodium) 75 µg/ml

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

20 ml vial

4. ROUTE(S) OF ADMINISTRATION

For intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD

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

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

Once opened, use by…

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET

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

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

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

2. 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]**

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Active substance:
D-cloprostenol (as D-cloprostenol sodium)..... 75 micrograms
Excipients:
Chlorocresol..... 1.0 mg

Clear colourless solution

4. INDICATIONS

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 females, 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. ADVERSE REACTIONS

Occurrence of bacterial infection is likely if anaerobic bacteria penetrate the tissue of the injection site. This applies in particular to cows.
Typical local reactions due to anaerobic infection are swelling and crepitus at the injection site.

When used in cows for induction of parturition and dependent on the time of treatment relative to the date of conception, the incidence of retained placenta may be increased.

Behavioural changes in sows seen after treatment for induction of farrowing are similar to those changes associated with natural farrowing and usually cease within 1 hour.

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

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 inform your veterinary surgeon.

7. TARGET SPECIES

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

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

Only for intramuscular use.

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

- Synchronisation of oestrus: administer the 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 product needs to be repeated 11 days after the first injection.
- Induction of parturition after day 270 of gestation: administer the 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 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 product in the first half of pregnancy.
- Expulsion of mummified foetus: administer 1 dose of the product. Expulsion of the foetus is observed within 3-4 days after administration of the 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

Prostaglandins can cause severe adverse reactions.

10. WITHDRAWAL PERIOD(S)

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 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.

12. SPECIAL WARNINGS

Special precautions for use in animals:
- 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:
Prostaglandins of the F2α type can be absorbed through the skin and may cause bronchospasm or miscarriage.
Care should be taken when handling the product to avoid self-injection or skin contact.
Women of child-bearing age, asthmatics and people with bronchial or other respiratory problems, should avoid contact with, or wear disposable impervious gloves when administering the product.
Accidental spillage on the skin should be washed off immediately with soap and water.

In case of accidental self injection seek medical advice immediately and show the package leaflet or the label to the physician.
Should shortness of breath result from accidental inhalation or injection, seek medical advice immediately and show the package leaflet or label to the physician.
Do not eat, drink or smoke while handling the product.

Use during pregnancy, lactation or lay:
The use in gestating animals produces abortion.

Interaction with other medicinal products and other forms of interaction:
Do not administer the 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 (symptoms, emergency procedures, antidotes):
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.

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

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

The veterinary medicinal product is packaged in type I colourless glass vial closed with bromobutyl rubber stopper and sealed with aluminium cap.

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.

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