[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NL: Planate 87.5 micrograms/ml solution for injection for pigs
BE, ES, FR, IE, LU: Planate 87.5 micrograms/ml, solution for injection
DE: Estrumate porcine 87.5 micrograms/ml, solution for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Cloprostenol 87.5 micrograms
(equivalent to 92 micrograms cloprostenol sodium).

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol	20 mg
Citric acid	
Sodium citrate dihydrate	
Sodium chloride	
Water for injection	

Clear colourless solution, practically free from particles.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (sows and gilts).

3.2 Indications for use for each target species

Induction of farrowing one or two days before the estimated date of parturition.

3.3 Contraindications

Do not use in pregnant animals in which the induction of parturition is not intended.
Do not administer to induce parturition in animals with suspected dystocia due to mechanical obstruction or abnormal position, presentation and/or posture of the foetus.
Do not use in cases of bronchospasm or gastrointestinal dysmotility.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

The response of sows and gilts to induction of parturition may be influenced by the physiological state and the time of treatment. The vast majority of the animals, 95%, will commence farrowing within 36 hours of treatment. The majority of animals can be expected to respond within the period of 24+/- 5 hours following the injection, except in those cases where spontaneous parturition is imminent.

3.5 Special precautions for use

Special precautions for safe use in the target species:

To reduce the risk of anaerobic infections arising from vasoconstriction at the injection site, injections into contaminated (wet or dirty) skin areas should be avoided. Thoroughly clean and disinfect injection sites prior to administration.

Injection into adipose tissue may lead to incomplete absorption of the veterinary medicinal product.

Premature induction of farrowing will reduce the piglet`s birth weight and increase the number of stillborn piglets and non-viable and immature born piglets. It is essential that the mean length of gestation is calculated on each farm from past records and not to anticipate the term of gestation by more than two days.

Do not administer intravenously.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Prostaglandins of the F2α type, such as cloprostenol, may 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 childbearing age, asthmatics and persons with other respiratory tract diseases should avoid contact when handling this veterinary medicinal product.
Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal product.

Accidental spillage on the skin should be washed immediately with soap and 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 label or leaflet to the physician.

This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to benzyl alcohol should avoid contact with the veterinary medicinal product.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs (sows and gilts):

Rare (1 to 10 animals / 10,000 animals treated)	Injection site infection[1];
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Restlessness[2], Frequent urination[2]; Diarrhoea[2] Retained placenta[3], Metritis[3], Dystocia[3], Stillbirth[3]

[1] May occur if anaerobic bacteria enter the injection site and may become generalized. Careful aseptic techniques should be employed to decrease the possibility of these infections.

[2] May be observed within 15 minutes post-injection and usually disappears after one hour.

[3] May be caused by induction of parturition with any exogenous compound.

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not administer to pregnant animals unless the objective is to terminate pregnancy.

Fertility:
There is no effect on the subsequent reproductive performance of sows treated with cloprostenol and of gilts or boars born from treated animals.

3.8 Interaction with other medicinal products and other forms of interaction

The concomitant use of oxytocin and cloprostenol increases the effects on the uterus.
Do not administer with non-steroidal anti-inflammatory drugs (NSAIDs) since they inhibit endogenous prostaglandin synthesis.
In animals to which a progestogen is being administered, a decrease in the response of cloprostenol can be expected.

3.9 Administration routes and dosage

To be administered by deep intramuscular route with a needle at least 4 cm long.
Administer a single dose of 2 ml per animal (equivalent to 175 micrograms of cloprostenol).

The stopper may be safely punctured up to 10 times. When treating groups of animals in one run, use a draw-off needle that has been placed in the vial stopper to avoid excess broaching of the stopper. The draw-off needle should be removed after treatment.

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

In general, an overdose can lead to the following symptoms: increased heart and respiratory rate, bronchoconstriction, increased body temperature, increased amounts of faeces and urine, salivation, nausea and vomiting. In worse cases transient diarrhoea may occur.

No antidotes are available: treatment should be symptomatic, assuming Prostaglandin F2α acts on smooth muscle cells.

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: 1 day.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QG02AD90

4.2 Pharmacodynamics

Cloprostenol sodium, a (racemic) analogue of prostaglandin $F_{2\alpha}$ ($PGF_{2\alpha}$), is a very potent luteolytic agent. It causes functional and morphological regression of the corpus luteum (luteolysis) followed by return to oestrus and normal ovulation.
Furthermore, this group of substances has a contractile effect on the smooth muscles (uterus, gastro-intestinal tract, respiratory tract, vascular system).
The veterinary medicinal product does not demonstrate any androgenic, oestrogenic or anti progesterone activity and its effect on pregnancy is due to its luteolytic property.
Unlike other prostaglandin analogues, cloprostenol has no thromboxane A_2 activity and does not cause platelet aggregation.

4.3 Pharmacokinetics

After intramuscular injection, cloprostenol is rapidly absorbed at peak concentrations of 1.07 ng/mL within 8 minutes. Subsequently, cloprostenol is rapidly eliminated for 1.5 hours followed by a slower elimination phase that results in concentrations below the detection limit between 4 and 6 hours after the administration.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Keep the vial in the outer carton in order to protect from light.
Do not freeze.

5.4 Nature and composition of immediate packaging

Colourless glass vial (Type I, Ph. Eur.), sealed with an ethyltetrafluoroethylene (ETFE) coated bromobutyl rubber stopper and secured with aluminium collars and flip-off caps.

Carton box containing 1 vial containing 20 ml solution for injection.
Carton box containing 1 vial containing 50 ml solution for injection.

Not all pack sizes may be marketed.

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.
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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NL: Planate 87.5 micrograms/ml solution for injection for pigs
BE, ES, FR, IE, LU: Planate 87.5 micrograms/ml, solution for injection
DE: Estrumate porcine 87.5 micrograms/ml, solution for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 87.5 micrograms cloprostenol.

3. PACKAGE SIZE

20 ml
50 ml

4. TARGET SPECIES

Pigs (sows and gilts)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Meat and offal: 1day.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.
Do not freeze.

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

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials of 20 and 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BE, ES, FR, IE, LU, NL: Planate
DE: Estrumate porcine

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains: 87.5 micrograms cloprostenol.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Used by: _____

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

NL: Planate 87.5 micrograms/ml solution for injection for pigs
BE, ES, FR, IE, LU: Planate 87.5 micrograms/ml, solution for injection
DE: Estrumate porcine 87.5 micrograms/ml, solution for injection for pigs

2. Composition

Each ml contains:

Cloprostenol	87.5 micrograms (equivalent to 92 micrograms cloprostenol sodium)
Benzyl alcohol	20 mg

Clear colourless solution, practically free from particles.

3. Target species

Pigs (sows and gilts)

4. Indications for use

Induction of farrowing one or two days before the estimated date of parturition.

5. Contraindications

Do not use in pregnant animals in which the induction of parturition is not intended.
Do not administer to induce parturition in animals with suspected dystocia due to mechanical obstruction or abnormal position, presentation and/or posture of the foetus.
Do not use in cases of bronchospasm, or the gastrointestinal dysmotility.
Do not use in cases of hypersensitivity to the active substance or any of the excipients.

6. Special warnings

Special warnings:
The response of sows and gilts to induction of parturition may be influenced by the physiological state and the time of treatment. The vast majority of the animals, 95%, will commence farrowing within 36 hours of treatment. The majority of animals can be expected to respond within the period of 24+/- 5 hours following the injection, except in those cases where spontaneous parturition is imminent.

Special precautions for safe use in the target species:
To reduce the risk of anaerobic infections Arising from vasoconstriction at the injection site, injections into contaminated (wet or dirty) skin areas should be avoided. Thoroughly clean and disinfect injection sites prior to administration.
Injection into adipose tissue may lead to incomplete absorption of the veterinary medicinal product.
Premature induction of farrowing will reduce the piglet`s birth weight and increase the number of stillborn piglets and non-viable and immature born piglets. It is essential that the mean length of gestation is calculated on each farm from past records and not to anticipate the term of gestation by more than two days.
Do not administer intravenously.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Prostaglandins of the F2α type, such as cloprostenol, may 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 childbearing age, asthmatics and persons with other respiratory tract diseases should avoid contact when handling this veterinary medicinal product. Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal product.
Accidental spillage on the skin should be washed immediately with soap and 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 label or leaflet to the physician.
This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to benzyl alcohol administer the veterinary medicinal product with caution.
Wash hands after use.

Pregnancy:
Do not administer to pregnant animals unless the objective is to terminate pregnancy.

Fertility:
There is no effect on the subsequent reproductive performance of sows treated with cloprostenol and of gilts or boars born from treated animals.

Interaction with other medicinal products and other forms of interaction:
The concomitant use of oxytocin and cloprostenol increases the effects on the uterus.
Do not administer with non-steroidal anti-inflammatory drugs (NSAIDs) since they inhibit endogenous prostaglandin synthesis.
In animals to which a progestogen is being administered, a decrease in the response of cloprostenol can be expected.

Overdose:
In general, an overdose can lead to the following symptoms: increased heart and respiratory rate, bronchoconstriction, increased body temperature, increased amounts of faeces and urine, salivation, nausea and vomiting. In worse cases transient diarrhoea may occur.
No antidotes are available: treatment should be symptomatic, assuming Prostaglandin F2α acts on smooth muscle cells.

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

7. Adverse events

Pigs (sows and gilts):

Rare (1 to 10 animals / 10,000 animals treated)	Injection site infection[1];
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Restlessness[2], Frequent urination[2]; Diarrhoea[2] Retained placenta[3], Metritis[3], Dystocia[3], Stillbirth[3]

[1] May occur if anaerobic bacteria enter the injection site and may become generalized. Careful aseptic techniques should be employed to decrease the possibility of these infections.

[2] May be observed within 15 minutes post-injection and usually disappears after one hour.

[3] May be caused by induction of parturition with any exogenous compound.

Reporting adverse events is important. It allows continuous safety monitoring of a 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

To be administered by deep intramuscular route with a needle at least 4 cm long.
Administer a single dose of 2 ml per animal (equivalent to 175 micrograms of cloprostenol).
The stopper may be safely punctured up to 10 times. When treating groups of animals in one run, use a draw-off needle that has been placed in the vial stopper to avoid excess broaching of the stopper. The draw-off needle should be removed after treatment."

9. Advice on correct administration

10. Withdrawal periods

Meat and offal: 1 day

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 freeze.

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 immediate packaging: 28 days.

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.

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

Carton box containing 1 vial containing 20 ml solution for injection.
Carton box containing 1 vial containing 50 ml solution for injection.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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:

Manufacturer responsible for batch release:
Vet Pharma Friesoythe GmbH
Sedelsberger Strasse 2
26169 Friesoythe
Lower Saxony
Germany

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.