SPC

PLANATE®

OTHER NAMES:
ESTRUMATE PORCINE

MSD Animal Health

ANNEX I

**SUMMARY OF
PRODUCT CHARACTERISTICS, LABELLING
AND PACKAGE LEAFLET**

CONTENTS

1.A SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Planate
Also known as: Estrumate Porcine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains

Active substance:

Cloprostenol Sodium	0.092 mg
(equivalent to Cloprostenol	0.087 mg)

Excipient:

Benzylalcohol	20 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
A clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (sows and gilts).

4.2 Indications for use, specifying each target species

A synthetic prostaglandin analogue for use in pigs as a luteolytic agent to induce parturition in sows and gilts.

4.3 Contraindications

Do not use in pregnant animals in which the induction of abortion or parturition is not intended.
Do not use in animals with spastic diseases of the respiratory or gastrointestinal tract.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Induction of farrowing too early in pregnancy can lead to non-viable piglets being born. An increase in the number of non-viable piglets may result if used more than two days prior to the average gestation length calculated from farm records.
Clean and disinfect injection sites thoroughly before injection to reduce risk of anaerobic infections.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Direct contact with skin or mucous membranes of the user should be avoided. Prostaglandins of the F2α type may 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.
Pregnant women, women of child-bearing age, asthmatics and persons with other respiratory tract diseases should exercise caution when handling cloprostenol. Those persons should avoid contact or wear disposable plastic gloves during administration of the product.
Accidental spillage on the skin should be washed off immediately with soap and water.
The possible incidence of bronchospasm with the product is unknown. Should shortness of breath result from accidental inhalation or injection, seek urgent medical advice and show the doctor this warning. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

The concomitant use of oxytocin and cloprostenol increases the effects on the uterus.

4.9 Amounts to be administered and administration route

A single 2 mL dose is given by deep intramuscular injection. It is recommended that a 1½ inch needle be used.
The average gestation length should be calculated on each farm from accurate service records. Sows and gilts may then be given Planate as early in gestation as 2 days before this calculated expected farrowing date.
Trials have shown that normally 95% of animals will commence farrowing within 36 hours of treatment. The majority of animals can be expected to respond within the period 24±5 hours following injection, except in those cases where spontaneous farrowing is imminent.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.
There are no antidotes available, treatment should be symptomatically, assuming that prostaglandin F2α influences the smooth muscle cells.

4.11 Withdrawal period(s)

Meat and offal: 1 day

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: prostaglandins
ATCvet code: QG02AD90
Cloprostenol, a synthetic prostaglandin analogue, structurally related to Prostaglandin F2α (PGF2α), is a potent luteolytic agent which provokes a morphological and functional regression (luteolysis) of the corpus luteum in pigs.

5.1 Pharmacodynamic properties

Closprostenol sodium is an analogue of prostaglandin F2α (PGF2α).
It is very much more potent than PGF2α as a luteolytic agent and when administered to pigs will cause functional and morphological regression of the corpus luteum (luteolysis) followed by return to normal oestrus cycling and ovulation.

5.2 Pharmacokinetic particulars

After its administration by injection, cloprostenol is metabolised to acid 9α, 11α, dihydroxy-15-ceto prost-5-enoic and 9α, 11α, 15-trihydroxyprost-5-enoic which rapidly disappears from the blood, being excreted via the urine in 5-6 hours.
Radiolabel studies show blood levels between 0.0014 and 0.002 μg per ml at 20 minutes - 2 hours after its administration. Subsequently, blood levels fall rapidly, having an apparent half life of 1-3 hours, falling below 0.00004 μg/ml at 8 hours. No significant concentrations are found at 24 hours in the liver, muscle, heart, kidneys, uterus, ovaries, skin, brain and fat.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzylalcohol
Sodium chloride
Sodium citrate
Citric acid
Water for injections

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months
Shelf life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 30°C
Protect from light.

6.5 Nature and composition of immediate packaging

20 and 50 mL colourless glass Type I vials , with synthetic ethyl tetrafluorethylene coated bromobutyl rubber type I bung secured with a pink flip cap.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

ANNEX II

PROPOSAL FOR LABELLING AND PACKAGE LEAFLET

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (BOX)
CARTON BOX/VIAL

NAME OF THE VETERINARY MEDICINAL PRODUCT

Planate

STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 mL of solution for injection contains:

Active substance(s):
Cloprostenol 0.0875 mg
(as Cloprostenol Sodium 0.092 mg)

PHARMACEUTICAL FORM

Solution for injection

PACKAGE SIZE

20mL and 50 mL

TARGET SPECIES

A synthetic prostaglandin analogue for use in pigs as a luteolytic agent to induce parturition in sows and gilts.

METHOD AND ROUTE OF ADMINISTRATION

Planate should be administered by deep intramuscular injection.
The average gestation length should be calculated on each farm from accurate service records. Sows and gilts may then be given Planate as early in gestation as 2 days before this calculated expected farrowing date.
Read the package leaflet before use.

WITHDRAWAL PERIOD

Meat and offal: 1 day

SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
Protect from light.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS

Any unused product or waste materials should be disposed of in accordance with local requirements.

FOR ANIMAL TREATMENT ONLY

For animal treatment only.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

READ THE PACKAGE LEAFLET BEFORE USE

Read the package leaflet before use.

MARKETING AUTHORISATION HOLDER

Product of Intervet International B.V., Boxmeer, The Netherlands

BATCH NUMBER

<Batch> <Lot> <BN> <number>

EXPIRY DATE

<EXP month/year>

PACKAGE LEAFLET

MSD Animal Health

NAME OF THE VETERINARY MEDICINAL PRODUCT

Planate

STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 mL of solution for injection contains:

Active substance:
Cloprostenol 0.0875 mg
(as Cloprostenol Sodium 0.092 mg)

Excipient(s):
Benzylalcohol 20 mg
For a full list of excipients, see section 6.1.

INDICATION(S)

A synthetic prostaglandin analogue for use in pigs as a luteolytic agent to induce parturition in sows and gilts.

CONTRAINDICATIONS

Do not use in pregnant animals in which the induction of abortion or parturition is not intended.
Do not use in animals with spastic diseases of the respiratory or gastrointestinal tract.

ADVERSE REACTIONS

None.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

TARGET SPECIES

Pigs (sows and gilts)

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

A single 2mL dose is given by deep intramuscular injection. It is recommended that a 1½ inch needle be used.
The average gestation length should be calculated on each farm from accurate service records. Sows and gilts may then be given Planate as early in gestation as 2 days before this calculated expected farrowing date.

Trials have shown that normally 95% of animals will commence farrowing within 36 hours of treatment. The majority of animals can be expected to respond within the period 24±5 hours following injection, except in those cases where spontaneous farrowing is imminent.

ADVICE ON CORRECT ADMINISTRATION

Clean and disinfect injection sites thoroughly before injection to reduce risk of anaerobic infections.

WITHDRAWAL PERIOD

Meat and offal: 1 day

SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 30°C.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton / vial.
Shelf life after first opening the container: 28 days

SPECIAL WARNING(S)

Special precautions for use in animals
Induction of farrowing too early in pregnancy can lead to non-viable piglets being born. An increase in the number of non-viable piglets may result if used more than two days prior to the average gestation length calculated from farm records.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Direct contact with skin or mucous membranes of the user should be avoided. Prostaglandins of the F2α type may 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.
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Use during pregnancy, lactation or lay
Do not administer to pregnant animals unless the objective is to terminate pregnancy.

Interaction with other medicinal products and other forms of interaction
The concomitant use of oxytocin and cloprostenol increases the effects on the uterus.

Overdose (symptoms, emergency procedures, 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.
There are no antidotes available, treatment should be symptomatically, assuming that prostaglandin F2α influences the smooth muscle cells.

Incompatibilities

Do not mix with any other veterinary medicinal product.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

Any unused product or waste materials should be disposed of in accordance with local requirements.

OTHER INFORMATION

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.

For animal treatment only.
Product of Intervet International B.V., Boxmeer, The Netherlands