PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box/20 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Planate 0.0875 mg/ml Solution for Injection
Cloprostenol

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 0.092 mg of cloprostenol sodium equivalent to 0.0875 mg cloprostenol, and 20 mg Benzyl alcohol as preservative.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

20 ml.

5. TARGET SPECIES

6. INDICATION(S)

Synthetic prostaglandin analogue for use in pigs as a luteolytic agent to induce farrowing in sows and gilts, thus providing opportunity for more efficient and convenient management under a variety of systems**.**

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Route: A single 2 ml dose given by deep intra-muscular injection.

8. WITHDRAWAL PERIOD

Withdrawal period: Meat and offal: 2 days.

9. SPECIAL WARNING(S), IF NECESSARY

For dosage, directions, warnings, precautions and disposal advice: Read package leaflet before use.
AVOID SELF-INJECTION OR SKIN CONTACT. Direct contact with mucous membranes of the user should be avoided.
Prostaglandins can cause severe adverse reactions. See package leaflet for full information. Wash hands after use.

10. EXPIRY DATE

Exp end of: {month/year}

11. SPECIAL STORAGE CONDITIONS

After first opening: Do not store above 30°C.
Keep vial in the outer carton in order to protect from light.
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12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]
For animal treatment only.

POM-V

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA holder in UK:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4579

7. MANUFACTURER'S BATCH NUMBER

Batch no: {number}
To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Label/20 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Planate 0.0875 mg/ml Solution for Injection
Cloprostenol

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

20 ml

4. ROUTE(S) OF ADMINISTRATION

For deep intramuscular injection in pigs.

5. WITHDRAWAL PERIOD

Withdrawal period: Meat and offal: 2 days.

6. BATCH NUMBER

Batch no.: {number}

7. EXPIRY DATE

Exp end of: {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only. Prostaglandins can cause severe adverse reactions.
To be supplied only on veterinary prescription.
Keep vial in the outer carton.
Read package leaflet before use.
In-use shelf life: 28 days
Once broached, use by . . . . . .

UK: MSD Animal Health UK Ltd., Milton Keynes, MK7 7AJ
POM-V Vm 01708/4579

PACKAGE LEAFLET FOR:

Planate 0.0875 mg/ml Solution for Injection

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

Marketing Authorisation Holder:
UK only:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Vet Pharma Friesoythe GmbH, Sedelsberger Str. 2-4, 26169
Friesoythe, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Planate 0.0875 mg/ml Solution for Injection
Cloprostenol

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each ml contains 0.092 mg of cloprostenol sodium equivalent to 0.0875 mg of cloprostenol and 20 mg benzyl alcohol as preservative.
A colourless injectable solution.

4. INDICATION(S)

A synthetic prostaglandin analogue for use in pigs as a luteolytic agent to induce farrowing in sows and gilts, to facilitate the management of farrowing.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

No side effects or adverse reactions are shown by the sow following injection of the drug at the recommended dose level.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)

- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs.

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

A single 2 ml dose is given by deep intramuscular injection. It is recommended that a 1½ inch needle be used.

9. ADVICE ON CORRECT ADMINISTRATION

Having calculated the average gestation length for each farm, sows and gilts may be injected two days before this date or on any date thereafter to suit the requirements of the particular management system. 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.
The product can be used under a variety of management systems to facilitate batch management of sows and gilts. This may help to minimise farrowing at antisocial times and planning husbandry around the farrowing period.
Planate should only be used where accurate service records are kept. If used too early in pregnancy induction of farrowing may lead to non-viable piglets being born. It is therefore essential that the average gestation length is calculated on each farm from past records, using the first day of service as Day 0, so that sows can be induced to farrow at the required time. In most situations gestation length varies between 111 and 119 days (average around 115 days).

10. WITHDRAWAL PERIOD(S)

Meat and offal: 2 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
After 1st opening: Do not store above 30°C. Keep 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 carton after EXP. The expiry date refers to the last day of the month.

12. 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 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your pharmacist how to dispose of medicines no longer required. These measures should help protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2021

15. OTHER INFORMATION>

For animal treatment only.
Pack size: Multidose vial containing 20 ml (10 doses).
UK only
Vm 01708/4579
POM-V
To be supplied only on veterinary prescription.

Approved 12 March 2021