SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Planate 0.0875 mg/ml Solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance	mg
Cloprostenol	0.0875
as Cloprostenol Sodium	0.092)

Excipients	
Benzyl alcohol	20 mg

For the full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection
A colourless, buffered sterile, aqueous solution

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (sows and gilts)

4.2 Indications for use

Parturition in sows and gilts, to facilitate the management of farrowing.

4.3 Contra-indications

None

4.4 Special warning for each target species

None

4.5 Special precautions for use

i. 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.

ii. 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.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant animals when parturition is not intended.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

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

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.

4.10 Overdose (symptoms, emergency procedures, antidotes)

No adverse reactions reported

4.11 Withdrawal period

Animals must not be slaughtered for human consumption during treatment.
Pigs may be slaughtered for human consumption only after 2 days from the last treatment.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet code: QG02AD90

Pharmacotherapeutic group: prostaglandins.

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.

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

ChlorocresolBenzyl alcohol
Sodium citrate
Citric acid anhydrous
Sodium chloride
Water for injections

6.2 Incompatibilities

None known

6.3 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

6.4 Special precautions for storage

Keep the vial in the outer carton in order to protect from light.
After 1st opening:
Do not store above 30 ºC.
Keep the vial in the outer carton in order to protect from light

6.5 Nature and composition of immediate packaging

20 ml colourless glass Type I vial, with bromobutyl ETFE coated stopper rubber bung with aluminium overseal.

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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4579

9. DATE OF FIRST AUTHORISATION

03 January 1996

10. DATE OF REVISION OF TEXT

March 2021

Approved 12 March 2021