Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Planate 0.0875 mg/ml Solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active Substance:

Cloprostenol	0.0875 mg
(as cloprostenol sodium	0.092 mg)

Excipients:

Benzyl alcohol (E1519)	20 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

A clear, colourless sterile aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the target species

A 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.

4.3 Contraindications

None.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Planate can be absorbed through the skin and therefore care should be taken when handling the product, especially by women of childbearing age and by asthmatics.
Accidental spillage on the skin should be washed immediately with plenty of water.
Wear disposal plastic gloves when administering the product. Wash hands after use.
Prostaglandins of the F_2alpha type may cause broncho-spasm in man, although the possible incidence of the effect with Planate is not known.

Should respiratory embarrassment result from accidental inhalation or injection, a rapid acting broncho-dilator, e.g. isoprenaline or salbutamol by inhalation is indicated.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

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.

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

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 2 ml 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.

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

Symptoms include restless behaviour (including pawing the ground, snout rubbing and kicking the chest). Frequent defecation may also be seen.

4.11 Withdrawal Period(s)

Meat and offal: 2 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Genito urinary system and sex hormones; prostaglandins.
ATCvet code: QG02AD90

5.1 Pharmacodynamic properties

Cloprostenol sodium is a (racemic) analogue of prostaglandin F_2alpha (PGF_2alpha).
It is very much more potent than PGF_2alpha as a luteolytic agent and when administered to cattle, horses and pigs will cause functional and morphological regression of the corpus luteum (luteolysis) followed by return to normal oestrus cycling and ovulation.
Pharmacological studies demonstrate that cloprostenol terminates pregnancy in rats, hamsters and guinea pigs. The drug does not demonstrate any androgenic, oestrogenic or anti progesterone activity and its effect on pregnancy is due to its luteolytic property. The drug is most active when administered subcutaneously and in the most sensitive species, the pregnant hamster, induces abortion at 1.25 microgram/kg compared to 25 microgram/kg orally.
Cloprostenol also causes abortion in pregnant marmosets but its mode of action in doing so is unknown.
At pharmacological doses, no obvious ill effects have been observed. Young rats dosed at about 50 times the effective dose, however did exhibit diarrhoea, a side-effect also seen in some of the dosed monkeys. Unlike other prostaglandin analogues, cloprostenol has no thromboxane A_2 activity and does not cause platelet aggregation.

5.2 Pharmacokinetic properties

Metabolism studies, using 15-^{14}C-cloprostenol have been performed in pigs and cattle (by IM administration) to determine residue levels to assess human hazard, and in the rat and marmoset (by SC administration) to determine the appropriateness of the species for toxicological evaluation of cloprostenol. The kinetics of cloprostenol following oral administration were not determined.

The kinetic studies, in both domestic and laboratory species, indicate that the compound is rapidly absorbed from the site of injection, is metabolised followed by excretion in approximately equal proportions in urine and faeces. In the cow and pig, a major portion of the dose is excreted within 0-4 hours and most of the dose is eliminated within 24 hours. The major route of metabolism in all species appears to be beta-oxidation to the tetranor or dinor acids of cloprostenol. Peak values of radioactivity in blood were observed within 1 hour of a parenteral dose and declined with a t ½ of between 1 - 3 hours depending on species.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Citric acid anhydrous
Sodium citrate
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 °C.
Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

20 ml Type I (clear) glass vials sealed with synthetic ethyl tetrafluoroethylene (ETFE) coated bromobutyl rubber stoppers secured with aluminium collars and pink flip-off caps.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/246/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1991

Date of last renewal: 30th September 2006

10 DATE OF REVISION OF THE TEXT

November 2016