

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON BOX**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Planate 87.5 micrograms/ml solution for injection

### **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: 1 day.

### **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**

Intervet International B.V.

**14. MARKETING AUTHORISATION NUMBER**

Vm 06376/3063

**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**

Planate

**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: \_\_\_\_\_

## **PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET**

### **PACKAGE LEAFLET**

#### **1. Name of the veterinary medicinal product**

Planate 87.5 micrograms/ml Solution for Injection

#### **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 F<sub>2α</sub> 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 child-bearing 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 F<sub>2α</sub> 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 <sup>1</sup> ;
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Restlessness <sup>2</sup> , Frequent urination <sup>2</sup> ; Diarrhoea <sup>2</sup> Retained placenta <sup>3</sup> , Metritis <sup>3</sup> , Dystocia <sup>3</sup> , Stillbirth <sup>3</sup>

<sup>1</sup> 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.

<sup>2</sup> May be observed within 15 minutes post-injection and usually disappears after one hour.

<sup>3</sup> 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:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

## **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.

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**

Vm 06376/3063

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. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

#### **16. Contact details**

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Vet Pharma Friesoythe GmbH  
Sedelsberger Strasse 2  
26169 Friesoythe  
Lower Saxony  
Germany

Contact details to report suspected adverse reactions:

##### **UK(GB)**

MSD Animal Health UK Ltd.  
Tel.: +44 (0)1908 685685

##### **UK(NI)**

Intervet Ireland Ltd.  
Tel.: +353 (0)1 2970220

Local representative:

MSD Animal Health UK Limited  
Walton Manor, Walton  
Milton Keynes  
MK7 7AJ  
United Kingdom

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

**17. Other information**

POM-V To be supplied only on veterinary prescription.

*Gavin Hall*  
Approved: 01 October 2025