

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box**

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

Bioestrovvet Swine 0.0875 mg/mL solution for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each mL contains:

Cloprostenol.....0.0875 mg

**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 periods: Meat and offal: 1 day.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached, use within 28 days.

Used by:

**9. SPECIAL STORAGE PRECAUTIONS**

Keep the vial in the outer carton in order to protect from light.

**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**

Vetoquinol UK Limited

**14. MARKETING AUTHORISATION NUMBERS**

Vm 08007/3000

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

Vial of 20 mL or 50 mL

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

Bioestrovvet Swine



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Each mL contains:  
Cloprostenol.....0.0875 mg

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 28 days.  
Used by: ...

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Bioestrovvet Swine 0.0875 mg/mL solution for injection for pigs

### 2. Composition

Each mL contains:

#### Active substance:

Cloprostenol.....0.0875 mg  
(equivalent to Cloprostenol Sodium..0.0920 mg)

#### Excipients:

Benzyl alcohol (E1519).....20.00 mg

A clear, colourless solution, free from visible 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 gastrointestinal dysmotility.  
Do not use in cases of hypersensitivity to the active substance or to 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, can 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 the veterinary medicinal product.

Personal protective equipment consisting of disposable 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 leaflet or the label to the physician.

This veterinary medicinal product may cause hypersensitivity (allergic) reactions. People with known hypersensitivity to benzyl alcohol should avoid contact with the veterinary medicinal product.

Wash hands after use.

Pregnancy:

Do not administer in pregnant animals unless the objective is to terminate the 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 amount 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 F2 $\alpha$  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):

<i>Rare (1 to 10 animals / 10 000 animals treated)</i>
Injection site infection <sup>1</sup>
<i>Very rare (&lt;1 animal / 10 000 animals treated, including isolated reports):</i>
Erythema <sup>2</sup> , Pruritus <sup>2</sup> Dyspnoea <sup>2</sup> , Hyperpnoea <sup>2</sup> Ataxia <sup>2</sup> , Muscle spasm <sup>2</sup> (abdominal) Vocalisation <sup>2</sup> , Nesting Behaviour <sup>2</sup> , Restlessness <sup>3</sup> Frequent urination <sup>3</sup> , Diarrhoea <sup>3</sup> , Involuntary defecation <sup>2</sup> , Hypersalivation <sup>2</sup> Retained placenta <sup>4</sup> , Metritis <sup>4</sup> , Dystocia <sup>4</sup> , Stillbirth <sup>4</sup>

<sup>1</sup> An anaerobic infection can occur when anaerobic bacteria enter the injection site, especially following intramuscular injection. This infection may become generalized. Careful aseptic techniques should be employed to decrease the possibility of these infections.

<sup>2</sup> Transient

<sup>3</sup> May be observed within 15 minutes post-injection and usually disappears after one hour.

<sup>4</sup> When used for induction of parturition and dependent on the time of treatment relative to the date of conception, as with any exogenous compound, the incidence of retained placenta, metritis, dystocia and stillbirth may be increased.

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 its local representative using the contact details at the end of this leaflet, or via your national reporting system:

## **8. Dosage for each species, routes and method of administration**

Intramuscular use.

To be administered by deep intramuscular route with a needle of at least 4-5 cm long.

A single dose of 0.175 mg cloprostenol (as cloprostenol sodium) per animal corresponding to 2 mL of product per animal.

The stopper may be safely punctured up to 10 times with a 21G needle (or finer). 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 use this veterinary medicinal product after the expiry date which is stated on the label and carton 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 or household waste.

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 number and pack sizes**

Vm 08007/3000

Cardboard box with 1 vial of 20 mL.  
Cardboard box with 1 vial of 50 mL.

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 or Local representative and contact details to report suspected adverse events:

Manufacturer responsible for batch release:

Vetoquinol S.A.  
Magny-Vernois  
70200 Lure  
France

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

*Gavin Hall*

Approved: 05 September 2025