

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bioestrovet Swine 0.0875 mg/mL solution for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains:

Active substance:

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

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzyl alcohol (E1519)	20.00 mg
Citric acid	
Sodium citrate	
Sodium chloride	
Water for injections	

A clear, colourless solution, free from visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (sows and gilts).

3.2 Indications for use for each target species

Induction of farrowing one or two days before the estimated date of parturition.

3.3 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.

3.4 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.

3.5 Special precautions for use

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_{2α}-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 any 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 leaflet or the label to the physician.

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

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs (sows and gilts):

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

¹ 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.

² Transient

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

⁴ 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Do not administer to 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.

3.8 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.

3.9 Administration routes and dosage

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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_{2α} acts on smooth muscle cells.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable

3.12 Withdrawal periods

Meat and offal: 1 day.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QG02AD90.

4.2 Pharmacodynamics

Cloprostenol sodium, a (racemic) analogue of prostaglandin F_{2α} (PGF_{2α}), is a very potent luteolytic agent. It causes functional and morphological regression of the corpus luteum (luteolysis) followed by return to oestrus and normal ovulation.

Furthermore, this group of substances has a contractile effect on the smooth muscles (uterus, gastrointestinal tract, respiratory tract, vascular system).

The veterinary medicinal product does not demonstrate any androgenic, oestrogenic or anti progesterone activity and its effect on pregnancy is due to its luteolytic property.

Unlike other prostaglandin analogues, cloprostenol has no thromboxane A₂ activity and does not cause platelet aggregation.

4.3 Pharmacokinetics

After intramuscular injection, cloprostenol is rapidly absorbed at peak concentrations of 1.07 ng/mL within 8 minutes.

Subsequently, cloprostenol is rapidly eliminated for 1.5 hours followed by a slower elimination phase that results in concentrations below the detection limit between 4 and 6 hours after the administration.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Type I colourless glass vial closed with bromobutyl rubber stopper coated with synthetic ethylene tetrafluoroethylene (ETFE) and sealed by an aluminium cap with a polypropylene flip-off.

Cardboard box with 1 vial of 20 mL.

Cardboard box with 1 vial of 50 mL.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10983/063/001

8. DATE OF FIRST AUTHORISATION

08/07/2022

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

19/06/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).