SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bioestrovet Swine 0.0875 mg/ml solution for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

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

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
A clear, colourless solution, free from visible particles.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (sows and gilts)

4.2 Indications for use, specifying the target species

In sows and gilts:
- Induction of farrowing from day 114 of pregnancy onwards (day 1 of pregnancy is the last day of insemination).

4.3 Contraindications

Do not use in pregnant animals unless the objective is to terminate the pregnancy.
Do not administer to animals with spastic disease of the respiratory or gastrointestinal tract.
Do not use in animals with cardiovascular, gastro-intestinal or respiratory disturbances.
Do not use to induce parturition in sows with suspected dystocia due to mechanical obstruction or if problems are expected because of an abnormal position of the foetus.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use intravenously.

4.4 Special warning for each target species

The response of sows and gilts to induction of parturition may be influenced by the physiological state at the time of treatment. Responses to treatment are not uniform either across herds or across individuals within herds.

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.
To reduce the risk of anaerobic infections, potentially related to the pharmacological properties of prostaglandins, avoid injecting through an area of contaminated skin.
Clean and disinfect carefully the injection sites before administration.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Prostaglandins of the F2-α type, such as cloprostenol, can be absorbed through the skin and mucous membranes 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 people with bronchial or other respiratory problems must avoid any contact with the product.
This veterinary medicinal product may cause hypersensitivity (allergic) reactions.
People with known hypersensitivity to benzyl alcohol should avoid contact with the product.
Wear disposable impervious gloves when administering the product.
Wash hands after use.
Accidental spillage on the skin should be washed off immediately with soap and water.
In case of accidental self-injection or spillage onto the skin, seek medical advice and show the package leaflet or label to the physician.
Should shortness of breath occur, seek medical advice immediately and show the package leaflet or label to the physician. Do not eat, drink or smoke while handling the product.

4.6 Adverse reactions (frequency and seriousness)

An anaerobic infection can occur when anaerobic bacteria enter the injection site, particularly following intramuscular injection.
When used in sows and gilts for induction of parturition and dependent on the time of treatment relative to the date of conception, the incidence of retained placenta may be increased.
In very rare cases transient erythema and pruritus, urination and defecation, ataxia, hyperpnea, dyspnea, nest-building behaviors, abdominal muscle spasms, vocalization and salivation may occur following the administration of prostaglandin F2α.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

Concomitant use of oxytocin and cloprostenol increases the effects on the uterus. Do not administer the product together with non-steroidal anti-inflammatory drugs since they inhibit endogenous prostaglandin synthesis.

4.9 Amounts to be administered and administration route

Intramuscular use.

A single dose of 0.175 mg cloprostenol (as cloprostenol sodium) per animal corresponding to 2 mL of product per animal once, by deep intramuscular injection, preferably with a needle of at least 4-5 cm long.

It is recommended that the vial is not broached more than 10 times with a 21G needle (or finer) and that the appropriate vial size is used for prevailing usage conditions. Otherwise, an automatic syringe equipment, or a suitable draw-off needle, should be used for the 50 ml vials to avoid excessive puncturing of the stopper.

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 carried out two days before the average term 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, and earlier if farrowing had already almost spontaneously begun.

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

Overdose can lead to the following symptoms: increased heart and respiratory rates, bronchoconstriction, increased body temperature, increased urine and faeces quantity, salivation, nausea and vomiting, restless behaviour.

There is no antidote.

4.11 Withdrawal period(s)

Meat and offal: 1 day

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: other gynecologicals; prostaglandins.
ATC Vet code: QG02AD90

5.1 Pharmacodynamic properties

Cloprostenol, a synthetic prostaglandin analogue, structurally related to Prostaglandin F2α (PGF2α), is a potent luteolytic agent which provokes morphological and functional regression (luteolysis) of the corpus luteum. In pregnant females, maintenance of pregnancy is dependent on progesterone secreted by the corpus luteum. Luteolysis at the end of gestation causes parturition.

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

Cloprostenol 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.

5.2 Pharmacokinetic particulars

After intramuscular injection, cloprostenol is rapidly absorbed with peaks of concentration usually reached within the first few minutes. The cloprostenol is then eliminated rapidly in less than 2 hours. A slow elimination phase follows with concentrations below quantifiable levels a few hours after administration. Intramuscular administration of 15-14C-cloprostenol show that cloprostenol is metabolised followed by excretion in approximately equal proportions in urine and faeces. 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 appears to be β-oxidation to the tetranor or dinor acids of cloprostenol.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Sodium citrate
Citric acid
Sodium chloride
Water for injections

6.2 Major incompatibilities

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

6.3 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

6.4 Special precautions for storage

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

6.5 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.

Pack sizes:
Cardboard box with 1 vial of 20 ml
Cardboard box with 1 vial of 50 ml

Not all pack sizes may be marketed.

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.
The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

8. MARKETING AUTHORISATION NUMBER

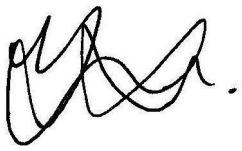
Vm 08007/3000

9. DATE OF FIRST AUTHORISATION

14 July 2022

10. DATE OF REVISION OF TEXT

July 2023



Approved: 07 July 2023