ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bioestrovet Swine 0.0875 mg/ml solution for injection for pigs
Cloprostenol

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Cloprostenol ..... 0.0875 mg/ml
(eq Cloprostenol sodium ..... 0.0920 mg/ml)

3. PHARMACEUTICAL FORM

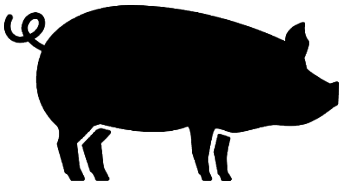
Solution for injection

4. PACKAGE SIZE

20 ml
50 ml

5. TARGET SPECIES

Pigs (sows and gilts)



6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: 2 days

9. SPECIAL WARNING(S), IF NECESSARY

User warnings: Prostaglandins can cause severe adverse reactions.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use by:
Once opened, use within 28 days

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 08007/5000

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 20 ml
Vial of 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bioestrovet Swine 0.0875 mg/ml solution for injection for pigs
Cloprostenol

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Cloprostenol ..... 0.0875 mg/ml
(eq Cloprostenol sodium .... 0.0920 mg/ml)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

I.M.

5. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 2 days

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once opened, use by: ...
Once opened use within 28 days

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

A. PACKAGE LEAFLET

PACKAGE LEAFLET:
Bioestrovet Swine 0.0875 mg/ml solution for injection for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Manufacturer responsible for batch release:
Vetoquinol S.A.
Magny-Vernois
70200 Lure
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bioestrovet Swine 0.0875 mg/ml solution for injection for pigs
Cloprostenol

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One ml contains:

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

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

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

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in pregnant animals unless the objective is to terminate the pregnancy.

Do not use in animals with cardiovascular, gastrointestinal 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.

6. ADVERSE REACTIONS

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.

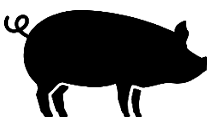
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)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

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system *{national system details}*.

7. TARGET SPECIES

Pigs (sows and gilts).



8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 2 days

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 vial and carton after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days

12. SPECIAL WARNING(S)

Special warnings for each target species:
The response of pregnant females 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.

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 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.

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

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.

Overdose (symptoms, emergency procedures, antidotes):
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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.
The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

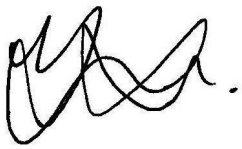
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{DD/MM/YYYY}

15. OTHER INFORMATION

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

Not all pack sizes may be marketed.



Approved: 27 January 2023