ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing a vial of 20 ml or 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cyclix Porcine solution for injection (87.5 microgram/ml).

2. STATEMENT OF ACTIVE SUBSTANCES

Cloprostenol sodium 92 µg/ml
(corresponding to 87.5 µg/ml cloprostenol)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

20 ml
50 ml

5. TARGET SPECIES

Sows.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

2 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

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

Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton.
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

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER

Vm 05653/5039

17. MANUFACTURER'S BATCH NUMBER

Batch : {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 20 ml or 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cyclix Porcine solution for injection (87.5 microgram/ml).

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Cloprostenol sodium 92 µg/ml
(corresponding to 87.5 µg/ml cloprostenol)

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

20 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

IM use.

5. WITHDRAWAL PERIOD

2 days.

6. BATCH NUMBER

Batch :{number}

7. EXPIRY DATE

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

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

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

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Cyclix Porcine solution for injection (87.5 microgram/ml)

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

Marketing authorisation holder and manufacturer responsible for batch release:
VIRBAC
1ère avenue 2065m LID
06516 Carros
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cyclix Porcine solution for injection (87.5 microgram/ml).

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

1 ml solution for injection contains:

Active substance(s):
Cloprostenol sodium 92 micrograms
(corresponding to 87.5 micrograms cloprostenol)

Excipients:
Benzyl alcohol (E1519) 20 mg

Colourless solution.

4. INDICATION(S)

Induction or synchronisation of farrowing (within 16 to 34 hours) from day 113 of pregnancy onwards (day 1 of pregnancy is the last day of natural or artificial insemination).

5. CONTRAINDICATIONS

Do not use in pregnant animals, for which induction of abortion or parturition is not intended. Do not use in the case of distocic parturition due to abnormal position of the foetus, mechanical obstruction, etc….
Do not use in animals with spastic diseases of the respiratory or gastrointestinal tract.

6. ADVERSE REACTIONS

Behavioural changes seen after treatment for induction of farrowing are similar to those changes associated with natural farrowing and usually cease within one hour.
Anaerobic infection may occur if anaerobic bacteria penetrate the tissue at injection site, in particular following intramuscular injection.

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

Sows.

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

2 ml corresponding to 0.175 mg cloprostenol/animal.
For intramuscular injection.
Single administration.

9. ADVICE ON CORRECT ADMINISTRATION

Deep intramuscular injection with a needle at least 4 cm long is recommended.

10. WITHDRAWAL PERIOD

Pig: Meat & offal: 2 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Keep the vial in the outer carton.
Protect from light.
Do not use after the expiry date stated on the outer carton.
After first opening the product may be stored for 28 days.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals
The product should only be used on farms where accurate insemination records are kept. Do not use before day 113 of pregnancy, as this may lead to increased mortality and reduced vitality of new-born piglets. Induction of labour before the 111th day of gestation may cause mortality in piglets and an increase in the number of sows that require manual assistance.

As with parenteral administration of any substance, basic aseptic rules should be observed. The injection site must be thoroughly cleaned and disinfected in order to reduce the risk of infection with anaerobic bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to benzyl alcohol should avoid contact with the product. Do not eat, drink or smoke while handling the product. Direct contact with skin or mucous membranes of the user should be avoided. Prostaglandins of the $F_{2\alpha}$ type may be absorbed through the skin and may cause bronchospasm or miscarriage. The product must be handled carefully to avoid ACCIDENTAL SELF-INJECTION OR SKIN CONTACT. Pregnant women, women in childbearing age, asthmatics and persons with other respiratory tract diseases should exercise caution when handling cloprostenol. Those persons should wear rubber (or plastic) gloves during administration of the product. Accidental spillage on the skin should be washed immediately with soap and water.
In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician.

Pregnancy and lactation
Do not use in pregnant animals, for which induction of abortion or parturition is not intended.
The safety of the veterinary medicinal product has not been established during lactation. There are no data suggesting negative effects of the treatment with cloprostenol on the course of lactation.

Interaction with other medicinal products and other forms of interaction
The activity of other oxytocic agents can be increased after the administration of cloprostenol.
Do not use in animals being treated with non-steroidal anti-inflammatories, as the synthesis of endogenous prostaglandins is inhibited.

Overdose (symptoms, emergency procedures, antidotes)
In general, overdose could result in the following symptoms: increased pulse and breathing rate, bronchoconstriction, increased body temperature, increased amounts of faeces and urine, salivation, nausea and vomiting.
There is no antidote.

Incompatibilities
Not known. Do not mix with other medicinal products.

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 how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2020

15. OTHER INFORMATION

Not all pack sizes may be marketed.

Approved: 06 July 2023