1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cyclix 87.5 µg/ml solution for injection for pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Cloprostenol 87.5 µg
as Cloprostenol sodium 92 µg

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 mg
Citric Acid Monohydrate (as a pH adjuster)	
Sodium Citrate	
Sodium Chloride	
Sodium Hydroxide (as a pH adjuster)	
Water for injections	

Colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (sows).

3.2 Indications for use for each target species

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).

3.3 Contraindications

Do not use in pregnant animals, for which induction of abortion or parturition is not intended. Do not use in the case of dystocic parturition (for example due to abnormal position of the foetus or mechanical obstruction).
Do not use in animals with spastic diseases of the respiratory or gastrointestinal tract.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The veterinary medicinal 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 veterinary medicinal product.
Do not eat, drink or smoke while handling the veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs (sows):

Undetermined frequency (cannot be estimated from the available data):	Behavioural disorder. * Injection site infection. **

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

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 also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not use in pregnant animals, for which induction of abortion or parturition is not intended.

Lactation:
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.

3.8 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.

3.9 Administration routes and dosage

Intramuscular use.
0.175 mg cloprostenol/animal corresponding to 2 ml of the veterinary medicinal product.
Single administration.
Deep intramuscular injection with a needle at least 4 cm long is recommended.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

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 & offal: 2 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QG02AD90

4.2 Pharmacodynamics

The Prostaglandin F2α analogue cloprostenol has luteolytic activity. Following its administration plasma progesterone falls to baseline levels. As a consequence, parturition is initiated and proceeds normally.
The effect of cloprostenol on the smooth muscular system is similar to that of Prostaglandin F2α itself.

4.3 Pharmacokinetics

Following injection, cloprostenol is rapidly absorbed and a peak plasma concentration of 1 ng/ml is reached within 8 min after injection. A very rapid elimination of cloprostenol then occurs until 1.5 hours, followed by a slower elimination phase leading to concentrations below quantifiable levels between 4 and 6 hours post-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
Protect from light.

5.4 Nature and composition of immediate packaging

20 ml or 50 ml colourless glass vials (glass type I, Ph.Eur.) closed with a halogenobutyl rubber stopper, with or without teflon coating.
An aluminium crimp cap with an integral plastic tamper-evident cover is fixed over the rubber stopper.

Package sizes:
Cardboard box containing one 20 mL vial
Cardboard box containing one 50 mL vial
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.
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

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{MM/YYYY}

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*).