Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Cyclix porcine 87.5 microgram/ml solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

1 ml solution for injection contains:

Cloprostenol sodium 92 micrograms
(corresponding to 87.5 micrograms cloprostenol)

Excipients:
Benzyl alcohol (E1519) 20 mg
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
Colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Sows.

4.2 Indications for use, specifying the 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).

4.3 Contraindications

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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 111^{th} 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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

2 ml corresponding to 0.175 mg cloprostenol/animal.

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

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

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.

4.11 Withdrawal period(s)

Pig: Meat & offal: 2 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Prostaglandins
ATCvet code: QG02AD90

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.

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Citric Acid Monohydrate As a pH adjuster
Sodium Citrate
Sodium Chloride
Sodium Hydroxide As a pH adjuster
Water for injections

6.2 Major incompatibilities

Not known.
Do not mix with other medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life of the veterinary product after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Keep the vial in the outer carton
Protect from light.

6.5 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.
Secondary packaging: cardboard box.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Virbac S.A.
1ère avenue
2065 M LID
06516 Carros
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10988/080/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 November 2005
Date of last renewal: 22 November 2010

10 DATE OF REVISION OF THE TEXT

July 2020