Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Cyclix 250 microgram/ml solution for injection for cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution for injection contains:

Active substance(s):

Cloprostenol sodium (corresponding to 250 micrograms cloprostenol)	263	micrograms

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

Cows.

4.2 Indications for use, specifying the target species

Induction of luteolysis allowing resumption of oestrus and ovulation in cyclic females when used during dioestrus, synchronisation of oestrus (within 2 to 5 days) in groups of cyclic females treated simultaneously, treatment of suboestrus and uterine disorders related to a functioning or persistent corpus luteum (endometritis, pyometra), treatment of ovarian luteal cysts, induction of abortion until day 150 of pregnancy, expulsion of mummified foetuses, induction of parturition.

4.3 Contraindications

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

Anaerobic infection may occur if anaerobic bacteria penetrate the tissue at injection site, in particular following intramuscular injection.
When used 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, anaphylactic-type reactions can be observed which might be life-threatening and require rapid medical care.

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 les 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, for which abortion or induction of parturition is not intended. The product can be safely used during lactation.

4.8 Interaction with other medicinal products and other forms of interactions

Concurrent use of oxytocin and cloprostenol increases effects on the uterus. 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

For all indications, 2 ml corresponding to 0.5 mg cloprostenol/animal, injected intramuscularly.
In order to synchronise oestrus in groups of females, it is recommended that the product is administered on two occasions with a between treatment interval of 11 days.

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

Therapeutic tolerance in cattle is broad. Overdoses of more than 10 times are generally well tolerated. Large overdoses may cause transient diarrhoea. No antidotes are available.
An overdose will not accelerate corpus luteum regression.

4.11 Withdrawal period(s)

Cattle:
Meat and offal: 2 days
Milk: Zero 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. Progesterone concentrations start to decrease as early as 2 hours following injection. As a consequence, females with a sensitive CL (i.e. at least 5 days old) return to oestrus within 2-5 days of treatment and ovulate.
The effect of cloprostenol on the smooth muscular system is similar to that of Prostaglandin F2α itself.

5.2 Pharmacokinetic particulars

Following intramuscular injection, cloprostenol is rapidly adsorbed and peak cloprostenol concentrations are generally reached within the first 15 minutes after injection. Blood cloprostenol concentrations steadily decrease with a mean half life of approx. 56 min.

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 as pH adjuster
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 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 and 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)

VPA10988/079/001

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

June 2020