SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevaprost 250 µg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Cloprostenol 250 micrograms
(equivalent to 263 micrograms cloprostenol sodium)

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	20.00 mg
Sodium citrate	
Citric acid	
Sodium chloride	
Sodium hydroxide	
Water for injections	

Clear, colourless solution, practically free from visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Cattle

3.2 Indications for use for each target species

Cattle (cows and heifers):
- Oestrus induction and synchronisation in cows and heifers with a functional corpus luteum.
- Induction of oestrus as an aid to management of suboestrus (‘silent heat’).
- Treatment of clinical and subclinical endometritis in the presence of a functional corpus luteum.
- Treatment of ovarian luteal cysts.
- Induction of abortion until day 150 of pregnancy.
- Induction of parturition after day 270 of gestation.

3.3 Contraindications

Do not administer the veterinary medicinal product to pregnant cows in which the induction of abortion or parturition is not intended.

Do not administer to induce parturition in animals with suspected dystocia due to mechanical obstruction or abnormal position, presentation and/or posture of the foetus.

Do not administer to animals with known hypersensitivity to the active substance or one of the excipients.

Do not use in animals with compromised cardiovascular function, bronchospasm or gastro-intestinal dysmobility. Do not administer intravenously.

3.4 Special warnings

In cattle, for the termination of pregnancy, best results are obtained before day 100 of gestation. Results are less reliable between day 100 and 150 of gestation.

There is a refractory period of four to five days after ovulation in cattle when females are insensitive to the luteolytic effect of prostaglandins.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Do not administer intravenously.

In case of oestrus induction: from the 2nd day after injection, adequate heat detection is necessary.

Induction of parturition and abortion may cause dystocia, stillbirth and/or metritis. The incidence of retained placenta may be increased depending on the time of treatment relative to the date of conception.

Premature induction of farrowing will reduce the piglet's birth weight and increase the number of stillborn piglets and non-viable and immature born piglets. It is essential that the mean length of gestation is calculated on each farm from past records and not to anticipate the term of gestation by more than two days.

To reduce the risk of anaerobic infections arising from vasoconstriction at the injection site, injections into contaminated (wet or dirty) skin areas should be. Clean and disinfect injection sites thoroughly before administration.

All animals should receive adequate supervision after treatment. Injection into adipose tissue can result in incomplete absorption of the veterinary medicinal product.

Cloprostenol may cause effects related to Prostaglandin F2α activity in the smooth muscles, such as increased frequency of urination and defecation.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Prostaglandins of the F2α type, such as cloprostenol, may be absorbed through the skin 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 childbearing age, asthmatics and persons with other respiratory tract diseases should avoid contact when handling this veterinary medicinal product. Personal protective equipment consisting of disposable impervious gloves should be worn when handling the veterinary medicinal product.

Accidental spillage on the skin should be washed immediately with soap and water. In case of accidental self-injection or spillage onto the skin seek medical advice immediately, particularly as shortness of breath may occur, and show the package leaflet or label to the physician.

This veterinary medicinal product may cause hypersensitive reactions. People with known hypersensitivity to benzyl alcohol should avoid contact with the veterinary medicinal product.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (cows and heifers)

Rare (1 to 10 animals / 10,000 animals treated)	Injection site infection[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis[2]; Increased respiratory rate[3]; Increased heart rate[3]; Abdominal pain[3], Diarrhoea[3,5]; Incoordination[3]; Lying down[3]; Retained placenta[4], Metritis[4], Dystocia[4], Stillbirth[4]; Restlessness, Frequent urination[3,5];

[1] May occur if anaerobic bacteria enter the injection site, especially following intramuscular injection, and may become generalized. Aggressive antibiotic therapy, particularly covering clostridial species, should be employed at the first sign of infection. Careful aseptic techniques should be employed to decrease the possibility of these infections.
[2] Requiring immediate medical attention. Can be life-threatening.
[3] Cloprostenol may cause effects similar to Prostaglandin F2α activity in the smooth muscles.
[4] May be caused by induction of parturition or abortion. As part of induction of parturition, depending on the date of treatment versus the date of conception, the incidence of placental retention may be increased.
[5] In case of occurrence, these effects are observed within 15 minutes post-injection and usually disappear after one hour.

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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

Lactation:

The product can be used during lactation.

Fertility:

Cloprostenol has a large safety margin and does not negatively affect fertility in cattle. Nor have any harmful effects been reported in the offspring of an insemination or mating following treatment with this veterinary medicinal product for conception products obtained after treatment.

3.8 Interaction with other medicinal products and other forms of interaction

The concomitant use of oxytocin and cloprostenol increases the effects on the uterus.

The concomitant use of progestogens decreases the effect of cloprostenol.

Do not administer the veterinary medicinal product together with non-steroidal anti-inflammatory drugs (NSAIDS) since they inhibit endogenous prostaglandin synthesis.

3.9 Administration routes and dosage

Intramuscular use.

Cattle (cows and heifers)

One dose equals 500 micrograms of cloprostenol/animal corresponding to 2 ml of the veterinary medicinal product per animal.

Oestrus induction and synchronisation

Administer one dose per animal. When no oestrus symptoms are observed, a second dose can be administered after 11 days.

Treatment of clinical and subclinical endometritis in the presence of a functional corpus luteum

Administer one dose of the veterinary medicinal product per animal. If necessary, repeat the treatment 10-14 days later.

Treatment of ovarian luteal cysts

Administer a single dose per animal

Induction of abortion up to day 150 of gestation

Administer a single dose of the veterinary medicinal product per animal, between the 5th and the 150th day of gestation .

Induction of parturition

Administer a single dose per animal not earlier than10 days before the expected date of calving.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

At x5 to x10 overdose the most frequent side effect is increased rectal temperature. This is usually transient, however, and not detrimental to the animal. Limited salivation may also be observed in some animals.
There are no antidotes available, treatment should be symptomatic, assuming that prostaglandin F2α influences the smooth muscle cells.

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

Cattle:
Meat and offal: 1 day.
Milk: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QG02AD90

4.2 Pharmacodynamics

Cloprostenol is a synthetic prostaglandin analogue structurally related to Prostaglandin F2α (PGF2α). As a potent luteolytic agent, at dosage of only 500 micrograms, it causes functional and morphological regression of the *corpus luteum* (luteolysis). Furthermore, this group of substances has a contractile effect on smooth muscles (uterus, gastrointestinal tract, respiratory tract, vascular system).

Cloprostenol does not demonstrate any androgenic, oestrogenic or anti-progesterone activity and its effects on pregnancy is due to its luteolytic property.

Unlike other prostaglandin analogues, cloprostenol has not tromboxane A2 activity and does not cause platelet aggregation. Cloprostenol has a good safety margin and does not impair fertility. No deleterious effects have been reported on the progeny conceived at the oestrus following treatment.

4.3 Pharmacokinetics

Studies of metabolism, using 15-14C-cloprostenol sodium, were conducted in swine and cattle (following I.M. administration) to determine residual levels.

Cloprostenol sodium is rapidly absorbed from the injection site. It is then metabolised and finally excreted practically similarly between urine and stool. In cattle less than 1% of the administered dose is eliminated via milk.

The main pathway of metabolization in all animal species appears to be that of β-oxidation with formation of the Tetranor-or dinor-acids of cloprostenol.

The values at the peak of radioactivity in the blood are observed within 1 hour of parenteral administration of sodium cloprostenol and tend to decrease with a $T_{1/2}$ between 1 and 3 hours (depending on the animal species).

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

Do not store above 25°C.
Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Clear, colourless glass (type I) vials sealed with bromobutyl rubber stoppers and aluminium flip-off caps, packed in a carton box.

Carton box with 1 x 10 ml vial
Carton box with 1 x 20 ml vial.
Carton box with 1 x 50 ml vial.
Carton box with 1 x 100 ml vial.
Carton box with 10 x 20 ml vials.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.
The veterinary medicinal product should not enter water courses as cloprostenol may be dangerous for fish and other aquatic organisms.
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

Ceva Sante Animale

7. MARKETING AUTHORISATION NUMBERS

Vm 14966/5057
Vm 14966/3056

8. DATE OF FIRST AUTHORISATION

21 September 2020

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

October 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall
Approved: 21 October 2025