

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

2.

Genestran 75 micrograms/ml solution for injection for cattle, horses and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

<u>Active substance:</u>	micrograms
R(+)-cloprostenol (as R(+)-cloprostenol sodium)	75
<u>Excipients:</u>	
Chlorocresol (as preservative)	1000

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection

A clear and odourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horses and pigs.

4.2 Indications for use, specifying the target species

Cattle:

- 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 (within the last two weeks of gestation).

Horses:

- induction of luteolysis in mares with a functional corpus luteum.

Pigs:

- induction or synchronisation of farrowing (generally within 24 to 36 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 case of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals with spastic respiratory or gastro-intestinal diseases.
Do not use in pregnant animals, for which induction of abortion or parturition is not intended.
Do not use for intravenous administration.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals:

To reduce the risk of anaerobic infections, which might be related to the pharmacological properties of prostaglandins, care should be taken to avoid injection through contaminated areas of skin. Clean and disinfect injection sites thoroughly before application.
Avoid contamination of the product during use. Should any apparent growth or discoloration occur, the product should be discarded.

Pigs: use only when precise date of insemination is known. Administer on day 113 of gestation, at the earliest. The product administered earlier, may impair the viability and weight of piglets.

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

The product must be handled carefully to avoid accidental self-injection and direct contact with the skin or mucous membranes of the user.. Prostaglandins of the F_{2α} type may be absorbed through the skin and may cause bronchospasm or miscarriage. Pregnant women, women of childbearing age, asthmatics and persons with other respiratory tract diseases should exercise caution when handling cloprostenol. Those persons should wear 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 leaflet or the label to the physician. Should respiratory distress result from accidental inhalation or injection, a rapid acting bronchodilator, e.g. isoprenaline or salbutamol by inhalation is indicated.

4.6 Adverse reactions (frequency and seriousness)

Anaerobic infections may occur if anaerobic bacteria are introduced into the tissue by the intramuscular injection.

Cattle:

Following induction of parturition with the product, an increased incidence of placental retention may be observed.

Horses:

After an injection of the product, slight sweating and diarrhoea may develop temporarily.

Pigs:

No undesirable effects have been reported.

4.7 Use during pregnancy, lactation or lay

Pregnancy:

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

Lactation:

Can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

For intramuscular administration only

Cattle:

2.0 ml (150 µg).

Induction of oestrus: two days following administration, close observation of the oestrus is advised.

Synchronisation of oestrus: animals are to be treated twice within 11 days.

Horses:

0.3- 0.5 ml (22.5 - 37.5 µg)

Intended for single use.

Pigs:

0.7- 1.0 ml (52.5 - 75 µg)

Intended for single use.

The stopper should not be pierced more than 70 times.

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

No specific antidote exists for R(+)- cloprostenol. For cattle and pigs no cases of overdosage have been recorded. An overdose of R(+)- cloprostenol in the horse may lead to transient diarrhoea, increased sweating around the neck and slight decrease in body temperature.

4.11 Withdrawal period(s)

Cattle and horses

Meat and offal: 1 day

Milk: zero hours

Pigs

Meat and offal: 1 day

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: prostaglandin-F2α-agonist
ATCvet code: QG02AD90

5.1 Pharmacodynamic properties

Genestran contains the active substance R(+) - cloprostenol, the biologically active component of the synthetic prostaglandin cloprostenol which acts similarly to the naturally occurring endogenous PGF_{2α}.

Since Genestran contains only the biologically active component R(+) - cloprostenol, low doses are sufficient to produce luteolytic and/or stimulatory effects on the myometrium.

5.2 Pharmacokinetic particulars

Cloprostenol is reabsorbed rapidly. As demonstrated in cattle, highest plasma concentrations (Tmax) are reached within one hour and decline with a t_{1/2} of between 40 to 80 minutes. Elimination occurs in the urine and faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Citric acid monohydrate
Sodium hydroxide (for pH adjustment)
Water for Injections

6.2 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 after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Colourless vials of type I glass containing 20 ml or 50 ml of solution for injection, with chlorobutyl rubber stoppers and aluminium caps.

Presentations:

Cardboard box of 1 vial of 20 ml or 50 ml
Cardboard box of 5 vials of 20 ml

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials

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

7. MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 24745/4010

9. DATE OF FIRST AUTHORISATION

27 November 2008

10. DATE OF REVISION OF THE TEXT

February 2017

A handwritten signature in black ink, consisting of several stylized, overlapping loops and a long, sweeping tail that curves downwards and to the right.

Approved 23 February 2017