1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
R(+)-cloprostenol (as R(+)-cloprostenol sodium) 75 micrograms

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Chlorocresol	1.0 mg
Citric acid monohydrate	
Sodium hydroxide	
Water for injections	

A clear and odourless solution for injection.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, pigs.

3.2 Indications for use for each 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).

3.3 Contraindications

Do not use in cases 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 veterinary medicinal product during use. Should any apparent growth or discoloration occur, the veterinary medicinal product should be discarded.
Pigs: use only when precise date of insemination is known. Administer on day 113 of gestation, at the earliest. The veterinary medicinal 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 veterinary medicinal 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 $F_{2\alpha}$ 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 the veterinary medicinal product. Those persons should wear 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. Should respiratory distress result from accidental inhalation or injection, a rapid acting bronchodilator, e.g. isoprenaline or salbutamol by inhalation is indicated.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle:

Undetermined frequency (cannot be estimated from the available data):	Injection site inflammation Injection site infection[1] Retained placenta[2]

[1] Anaerobic infections may occur after introduction of anaerobic bacteria into the tissue by intramuscular injection.
[2] Following induction of parturition.

Horses:

Undetermined frequency (cannot be estimated from the available data):	Injection site inflammation Injection site infection[1] Increased sweating[2] Diarrhoea[2]

[1] Anaerobic infections may occur after introduction of anaerobic bacteria into the tissue by intramuscular injection.
[2] Slight; temporarily.

Pigs:

Undetermined frequency (cannot be estimated from the available data):	Injection site inflammation Injection site infection[1]

[1] Anaerobic infections may occur after introduction of anaerobic bacteria into the tissue by 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 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:
Can be used during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

Intramuscular use.

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.

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

No specific antidote exists for R(+)- cloprostenol. For cattle and pigs no cases of over-dosage 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.

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 and horses:
Meat and offal: 1 day.
Milk: zero hours.

Pigs:
Meat and offal: 1 day.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QG02AD90

4.2 Pharmacodynamics

The veterinary medicinal product contains the active substance R(+) - cloprostenol, the biologically active component of the synthetic prostaglandin cloprostenol which acts similarly to the naturally occurring endogenous $PGF_{2\alpha}$.
Since the veterinary medicinal product contains only the biologically active component R(+) - cloprostenol, low doses are sufficient to produce luteolytic and/or stimulatory effects on the myometrium.

4.3 Pharmacokinetics

Cloprostenol is reabsorbed rapidly. As demonstrated in cattle, highest plasma concentrations (Tmax) are reached within one hour and decline with a t½ of between 40 to 80 minutes. Elimination occurs in the urine and faeces.

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 in order to protect from light.

5.4 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.

Pack sizes:
Cardboard box with 1 vial of 20 ml
Cardboard box with 1 vial of 50 ml
Cardboard box with 5 vials of 20 ml

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

aniMedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10826/010/001

8. DATE OF FIRST AUTHORISATION

09/10/2009

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

16/08/2024

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).