

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Genestran 75 micrograms/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

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

3. PACKAGE SIZE

20 ml

50 ml

5 x 20 ml

4. TARGET SPECIES

Cattle, horses, pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

User warning: contact with the mucosa and accidental injection are dangerous.

7. WITHDRAWAL PERIODS

Withdrawal period:

Cattle and horses

Meat and offal: 1 day.

Milk: zero hours.

Pigs

Meat and offal: 1 day.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

POM-V (Veterinary medicinal product subject to prescription).

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 24745/5002

Vm 24745/3002

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Label 50ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Genestran 75 micrograms/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

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

3. TARGET SPECIES

Cattle, horses, pigs.

4. ROUTES OF ADMINISTRATION

Intramuscular use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle and horses

Meat and offal: 1 day.

Milk: zero hours.

Pigs:

Meat and offal: 1 day.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH

9. BATCH NUMBER

Lot {number}

POM-V (Veterinary medicinal product subject to prescription)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {Label 20 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Genestran 75 micrograms/ml solution for injection

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:

Active substance:

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

POM-V

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:

R(+)-cloprostenol (as R(+)-cloprostenol sodium) 75 micrograms

Excipients:

Chlorocresol (as preservative) 1.0 mg

A clear and odourless solution for injection.

3. Target species

Cattle, horses, pigs.

4. Indications for use

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).

5. 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.

6. Special warnings

Special precautions for safe use in the target species:

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_{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 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.

Pregnancy:

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

Lactation:

The product can be used during lactation.

Interaction with other medicinal products and other forms of interaction:

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

Overdose:

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.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Cattle:

Undetermined frequency (cannot be estimated from the available data):	Injection site inflammation Injection site infection ¹ Retained placenta ²
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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
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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
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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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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)

Pigs:

0.7- 1.0 ml (52.5 - 75 µg)

The stopper should not be pierced more than 70 times.

9. Advice on correct administration

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. Do not use the veterinary medicinal product if you notice any apparent growth or discoloration of the solution.

10. Withdrawal periods

Cattle and horses

Meat and offal: 1 day.

Milk: zero hours.

Pigs

Meat and offal: 1 day.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label after "Exp". The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days. When the container is broached for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 24745/5002

Vm 24745/3002

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder:

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Manufacturer responsible for batch release:

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell

Germany

Industrial Veterinaria S.A.
Esmeralda 19
08950 Esplugues de Llobregat
(Barcelona)
Spain

Local representatives and contact details to report suspected adverse reactions:

Forte Healthcare Ltd.
Naul, Co. Dublin, Ireland

17. Other information

POM-V
For animal treatment only.

Gavin Hall
Approved: 17 January 2025