

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE :
Box 1 x 20 ml, 1 x 50 ml, 5 x 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Genestran 75 micrograms/ml solution for injection for cattle, horses and pigs
R(+)-cloprostenol

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
75 micrograms R(+)-cloprostenol (as R(+)-cloprostenol sodium) and 1 mg
chlorocresol as preservative.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

20 ml
50 ml
5 x 20 ml

5. TARGET SPECIES

Cattle, Horses, Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period
Cattle and horses
Meat and offal: 1 day
Milk: zero hours

Pigs
Meat and offal: 1 day

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP: {MM/YYYY}

Once broached, use by ... / ... / ...

Shelf-life after first broaching the container: 28 days

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste materials in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 24745/4010

17. MANUFACTURER’S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label 20ml, 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Genestran 75 micrograms/ml solution for injection for cattle, horses and pigs
R(+)-cloprostenol

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains:
75 micrograms R(+)-cloprostenol (as R(+)-cloprostenol sodium) and 1 mg chlorocresol as preservative.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

For intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Withdrawal period:

Cattle and horses

Meat and offal: 1 day

Milk: zero hours

Pigs

Meat and offal: 1 day

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP: {MM/YYYY}

Once broached, use by ... / ... / ...

Shelf-life after first broaching the container: 28 days

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only. To be supplied only on veterinary prescription.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

OR

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Genestran 75 micrograms/ml solution for injection for cattle, horses and pigs
R(+)-cloprostenol

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

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

<u>Excipients:</u>	
Chlorocresol (as preservative)	1000

A clear and odourless solution.

4. INDICATIONS

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 fetuses
- 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 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.

6. ADVERSE REACTIONS

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.

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, horses, pigs

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

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)

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.

10. WITHDRAWAL PERIOD

Cattle and horses

Meat and offal: 1 day

Milk: zero hours

Pigs

Meat and offal: 1 day

11. SPECIAL STORAGE PRECAUTIONS

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after "EXP". The expiry date refers to the last day of that month. Keep the vial in the outer carton in order to protect from light. Keep out of the sight and reach of children. Avoid contamination of the product during use. Should any apparent growth or discoloration occur, the product should be discarded. Shelf-life after first opening of the container: 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. This discard date should be written in the space provided on the label.

12. SPECIAL WARNINGS

Special precautions for use in animals

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 $F_{2\alpha}$ 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 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.

Lactation

The product can be used during lactation.

Overdose (symptoms, emergency procedures, antidotes)

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.

Incompatibilities

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

Interaction with other medicinal products and other forms of interaction

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Properties and effects

As its active agent, Genestran contains R(+)- cloprostenol, the biologically active component of the synthetic prostaglandin cloprostenol, which acts similarly to the naturally occurring endogenous $PGF_{2\alpha}$. As Genestran contains only the biologically

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

Presentations: 1 x 20 ml, 1 x 50 ml and 5 x 20 ml vials
Not all pack sizes may be marketed.

Vm 24745/4010

A handwritten signature in black ink, consisting of several vertical strokes followed by a horizontal line that curves upwards to the right.

Approved 01 May 2019