PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PGF Veyx forte 0.250 mg/ml solution for injection for cattle and pigs

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml solution contains 0.250 mg cloprostenol (equivalent to 0.263 mg cloprostenol sodium).

3. PACKAGE SIZE

10 ml
20 ml
50 ml

4. TARGET SPECIES

Cattle (cows and heifers), pigs (sows).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Cattle:	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

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

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.

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

Veyx-Pharma GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 27569/4002

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vials, 10 ml, 20 ml and 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PGF Veyx forte

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 ml solution contains: 0.250 mg cloprostenol

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Use by: _____

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

PGF Veyx forte 0.250 mg/ml solution for injection for cattle and pigs

2. Composition

Each ml solution contains 0.250 mg cloprostenol (equivalent to 0.263 mg cloprostenol sodium) and 1.00 mg chlorocresol.

Clear, colourless aqueous solution

3. Target species

Cattle (cows and heifers), pigs (sows).

4. Indications for use

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 (inflammation of the uterus).
- Treatment of ovarian luteal cysts.
- Induction of parturition after day 270 of gestation.
- Induction of abortion up to day 150 of gestation.

Pigs (sows):
- Induction of farrowing one or two days before the estimated date of parturition.

5. Contraindications

Do not use in pregnant animals in which the induction of abortion or parturition is not intended.
Do not administer to induce parturition in animals with suspected dystocia (difficult parturition) due to mechanical obstruction or abnormal position, presentation and/or posture of the foetus.
Do not use in animals with compromised cardiovascular function, bronchospasm or gastrointestinal dysmotility.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

There is a refractory period of several days after ovulation (e.g. four to five days in cattle), when females are insensitive to the luteolytic effect of prostaglandins.
For the termination of gestation in cattle, best results are obtained before day 100 of gestation. Results are less reliable between day 100 and 150 of gestation.

The response of sows to induction of parturition may be influenced by the physiological state and the time of treatment. The vast majority of animals, 95%, will commence farrowing within 36 hours of treatment. The majority of animals can be expected to respond within the period of 24+/- 5 hours following the injection, except in those cases where spontaneous parturition is imminent.

Special precautions for safe use in the target species:
To reduce the risk of anaerobic infections arising from vasoconstriction at the injection site, injections into contaminated (wet or dirty) skin areas should be avoided.
Thoroughly clean and disinfect injection sites prior to administration.
Do not administer intravenously.
All animals should receive adequate supervision after treatment.
Induction of parturition or abortion may cause dystocia (difficult parturition), stillbirth and/or metritis (inflammation of the uterus). 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.
Injection into adipose tissue can result in incomplete absorption of the veterinary medicinal product.
Cloprostenol may cause effects related to prostaglandin $F_{2\alpha}$ 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 $F_{2\alpha}$ type, such as cloprostenol, may be absorbed through the skin and may cause bronchospasm or miscarriage. Care should be taken when handling the veterinary medicinal 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 impervious gloves should be worn when handling the veterinary medicinal product.
Accidental spillage on the skin should be washed off 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 chlorocresol should avoid contact with the veterinary medicinal product.

Wash hands after use.

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

Lactation:
The veterinary medicinal 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.

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 with non-steroidal anti-inflammatory drugs (NSAIDs) since they inhibit endogenous prostaglandin synthesis.

Overdose:
Cattle: At 5x to 10x overdose the most frequent side effect is increased rectal temperature. This is usually transient, however, and not detrimental to the animal. Limited salivation or transient diarrhoea may also be observed in some animals.
Pigs: In general, an overdose can lead to the following symptoms: increased heart and respiratory rate, bronchoconstriction, increased body temperature, increased amounts of faeces and urine, salivation, nausea and vomiting. In worse cases transient diarrhoea may occur.
There are no antidotes available, treatment should be symptomatic, assuming that prostaglandin $F_{2\alpha}$ influences the smooth muscle cells.

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 (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 $F_{2\alpha}$ 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.

Pigs (sows):

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 $F_{2\alpha}$ activity in the smooth muscles.
[4] May be caused by induction of parturition. 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 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:
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

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

Intramuscular use.

Cattle (cows and heifers):
One dose equals 500 micrograms of cloprostenol per animal, corresponding to 2 ml of the veterinary medicinal product.

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 (inflammation of the uterus):
Administer one dose per animal. If necessary, repeat the treatment 10-14 days later.

Treatment of ovarian luteal cysts:
Administer a single dose per animal.

Induction of parturition:
Administer a single dose per animal, not earlier than 10 days before the expected date of calving.

Induction of abortion up to day 150 of gestation:
Administer a single dose per animal between the 5th and the 150th day of gestation.

Pigs (sows):
One dose equals 175 micrograms of cloprostenol per animal, corresponding to 0.7 ml of the veterinary medicinal product.

Induction of farrowing:
Administer a single dose per animal one or two days before the estimated date of parturition (see also warnings in section 3.5).
To be administered by deep intramuscular route with a needle at least 4 cm long.

The rubber stopper of the vial may be safely punctured up to 25 times. When treating groups of animals in one run, use a draw-off needle that has been placed in the vial stopper to avoid excess broaching of the stopper, or use automatic syringe equipment for the 50 ml vials. The draw-off needle should be removed after treatment.

9. Advice on correct administration

None

10. Withdrawal periods

Cattle:
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.
Do not store above 25°C.
Protect from light.
Keep the vial in the outer carton.
Shelf life after first opening the immediate packaging: 28 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 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 27569/4002

1 vial (10 ml) in a cardboard box
1 vial (20 ml) in a cardboard box
1 vial (50 ml) in a cardboard box

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, manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Veyx-Pharma GmbH
Söhreweg 6
34639 Schwarzenborn
Germany
Tel: +49 5686 9986 62
E-mail: pharmacovigilance@veyx.de

Manufacturer responsible for batch release
Veyx-Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

Local representative and contact details to report suspected adverse reactions:

GB:
ANUPCO Ltd. T/A Kela Animal Health UK
Office 39
Lodge House, Lodge Park, Lodge Lane
Langham, Colchester
Essex, CO4 5NE
England
Tel: +44 (0) 1206 233528
E-mail: sales@kela.health

NI:
Kela Veterinaria nv
Nieuwe Steenweg 62
9140 Elversele
Belgium
Tel.: +32 (0)3 780 63 90
E-mail: info.vet@kela.health

17. Other information

POM-V

Gavin Hall
Approved: 10 June 2026