PGF Veyx®
PGF Veyx® forte

Cloprostenol 0.0875 mg/ml

Cloprostenol 0.250 mg/ml

- Therapy of oestrus disorders and uterine diseases
- Control of farrowing dates
- Synchronisation of the oestrous cycle, induction of abortion and parturition in cattle
- Reliable luteolysis
- Hardly any adverse reactions

The active substance cloprostenol contained in PGF Veyx® and PGF Veyx® forte belongs to the group of prostaglandin $F_{2\alpha}$-agonists that exhibit luteolytic effect depending on the species and the time of administration. In addition, this group of active substances exhibits contractile activity on the smooth musculature (uterus, gastrointestinal tract, respiratory tract, vascular system).

The luteolytic effect of cloprostenol is 200- to 400-fold higher than that of prostaglandin $F_{2\alpha}$. Its effect on the smooth musculature, however, is comparable to that of prostaglandin $F_{2\alpha}$.

The administration of $PGF_{2\alpha}$ -agonists such as PGF Veyx® or PGF Veyx® forte during dioestrus or in the case of persisting corpus luteum leads to luteolysis. The resulting termination of the negative feedback mechanism caused by progesterone initiates the premature onset of oestrus and ovulation in animals with cyclic ovarian functions. The mode and duration of administration of $PGF_{2\alpha}$ agonists in cattle within the scope of the so-called 'Ovsynch procedure' is described in detail in the catalogue sheet of the product Gonavet Veyx®.

Through the treatment with $PGF_{2\alpha}$ -agonists, abortion or birth can also be induced in the case of dead foetuses (e. g. mummified or macerated foetuses) or hydramnion/ hydrallantois.

In cattle it is possible to stimulate lung maturation of the foetus and to reduce the incidence of respiratory distress syndrome in the premature calf through the application of $PGF_{2\alpha}$ -agonists to the dam where interruption of gestation is required (e. g. due to severe diseases of the dam) at least 24 hours before the planned date of birth. However, in cattle of the "German Black Pied" breed this measure is mostly successful only at a gestational age of at least 258 days.

The instructions for use of the products PGF Veyx® and PGF Veyx® forte are summarised below. Both preparations have marketing approval for the species cattle and pigs and only differ in the concentration of the active substance and consequently in the dosage rates.

PGF Veyx® 0.0875 mg/ml

Solution for injection for cattle and pigs
Cloprostenol

and

PGF Veyx® forte 0.250 mg/ml

Solution for injection for cattle and pigs
Cloprostenol

Active substances and other ingredients
1 ml solution for injection contains:

PGF Veyx®
Active substance:
Cloprostenol 0.0875 mg (corresponding to 0.092 mg cloprostenol sodium)
Excipients:
Chlorocresol 1.0 mg

and

PGF Veyx® forte
Active substance:
Cloprostenol 0.250 mg (corresponding to 0.263 mg/ml cloprostenol sodium)
Excipients:
Chlorocresol 1.0 mg

Indications

Cattle (heifers, cows):

- To schedule the time of oestrous and ovulation and for cycle synchronisation in animals with an ovulatory cycle when applied during the dioestrus (induction of oestrus in non-detected oestrus, synchronisation of oestrus)
- Treatment of anoestrus and uterine disorders caused by a progesterone-induced oestrous cycle blockade (induction of oestrous in anoestrus, endometritis, pyometra, corpus luteal cysts, follicular luteal cysts, shortening of the sexual rest period)
- Induction of abortion up to day 150 of pregnancy
- Expulsion of mummified foetuses
- Induction of parturition

Pigs (sows):

- Induction or synchronisation of farrowing from day 114 of pregnancy onwards (day 1 of pregnancy is the last day of insemination)

Contraindications

- Do not use for intravenous administration
- Do not use in pregnant animals where the induction of abortion or parturition is not intendend
- Do not use in case of spastic diseases of the respiratory tract and gastrointestinal tract
- Do not use in cases of hypersensitivity to the active substance or to any of excipients

Adverse reactions

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

Cattle:

When used for induction of parturition, the incidence of retained placenta may be increased depending on the time of treatment.
In very rare cases, anaphylactic-type reactions can be observed which might be life threatening and require rapid medical care.

Pig:

The abnormal behaviour that might occur in pigs immediately after treatment, when the drug has been used to induce parturition, is similar to that of sows before normal birth and normally subsides within one hour.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

If you notice any side effects, even those not listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Target species
Cattle (heifers, cows) and pigs (sows)

Dosage for each species, routes and method of administration
PGF Veyx®
For intramuscular injection in cattle (heifers, cows).
For deep intramuscular injection in pigs (sows) (with a needle at least 4 cm long).

Cattle (heifers, cows):
0.5 mg Cloprostenol/animal corresponding to 5.7 ml of the product/animal

In order to synchronise oestrus in a cattle herd, it is recommended that the product is administered on two occasions with an 11-day interval between treatments.

Pigs (sows):
0.175 mg Cloprostenol/animal corresponding to 2.0 ml of the product/animal

Single administration.

PGF Veyx forte®
For intramuscular injection in cattle (heifers, cows).
For deep intramuscular injection in pigs (sows) (with a needle at least 4 cm long).

Cattle (heifers, cows):
0.5 mg Cloprostenol/animal corresponding to 2.0 ml of the product/animal

In order to synchronise oestrus in a cattle herd, it is recommended that the product is administered on two occasions with an 11-day interval between treatments.

Pigs (sows):
0.175 mg Cloprostenol/animal corresponding to 0.7 ml of the product/animal

Single administration.

Use automatic syringe equipment for the 50 ml vials.

The rubber stopper of the vial may be safely punctured up to 25 times. Otherwise, automatic syringe equipment, or a suitable draw-off needle, should be used for the 50 ml vials to avoid excessive puncturing of the closure.

Advice on correct administration
None.

Withdrawal period

Cattle, pigs:	Meat and offal	2 days
Cattle:	Milk	Zero hours

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.

Do not use after the expiry date stated on the vial and carton.
Shelf life after first opening the container: 28 days.
When the container is broached (opened) 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 vial should be discarded should be worked out. This discard date should be written in the space provided on the label.

Special warnings
Special warnings for each target species:
None.

Special precautions for use:
Special precautions for use in animals:
To reduce the risk of anaerobic infections care should be taken to avoid injection through contaminated areas of skin. Clean and disinfect injection sites thoroughly before application.

Pigs:
Use only if the cover dates are known. Too early an administration could adversely affect the viability of the piglets. This is the case when the injection is given more than 2 days before the average gestation period of the stock. Day 1 of pregnancy is the last day of insemination. The gestation period is generally 111-119 days.

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

- This product must be handled carefully to avoid accidental self-injection or 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 in childbearing age, asthmatics and people with other respiratory tract diseases should wear waterproof gloves during administration of the product.
- Accidental spillage on the skin should be washed off 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.

Use during pregnancy, lactation or lay:
Do not use in pregnant animals when abortion or induction of parturition is not intended.
Safety of the product has not been established during lactation.
Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction
Concurrent use of oxytocin and cloprostenol increases the effects on the uterus.
Do not use in animals being treated with non-steroidal anti-inflammatories, as the synthesis of endogenous prostaglandins is inhibited.

Overdose (symptoms, emergency procedures, antidotes), if necessary:
In case of overdose the following symptoms may occur:
Increased heart rate, increased respiratory rate, bronchoconstriction, increased rectal temperature, increased defecation and urination, salivation, nausea and vomiting.
No antidotes are available.

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

Special precautions for the disposal of unused product or waste materials, if any

Medicines should not be disposed of via wastewater. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

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

To be supplied only on veterinary prescription.

Package sizes

PGF Veyx® 50 ml vial

PGF Veyx® forte 10 ml, 20 ml and 50 ml vial

The information given in this catalogue sheet corresponds to the state of knowledge upon completion. Please, kindly thoroughly read the product information prior to use.

Literature is available upon request.

Veyx-Pharma is GMP- and QS-certified.

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