

*[Version 9,03/2022] corr. 11/2022*

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AT, BE, BG, CZ, DE, EE, EL, ES, FR, HU, IE, IT, LT, LU, LV, NL, PT, RO, SI, SK, UK: PGF Veyx  
0.0875 mg/ml solution for injection for cattle and pigs

PL: Cloprostenol Veyx 0.0875 mg/ml solution for injection for cattle and pigs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substance:

Cloprostenol 0.0875 mg  
(equivalent to 0.092 mg cloprostenol sodium)

### 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 chloride  |   |
| Sodium hydroxide (for pH adjustment)                         |   |
| Sodium citrate   |   |
| Water for injections   |   |

Clear, colourless aqueous solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

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

### 3.2 Indications for use for each target species

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.
- 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.

### 3.3 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 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.

### **3.4 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  $24 \pm 5$  hours following the injection, except in those cases where spontaneous parturition is imminent.

### **3.5 Special precautions for use**

#### 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, stillbirth and/or metritis. 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.

#### Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Cattle (cows and heifers):

|  |   |
|--|---|
| Rare<br>(1 to 10 animals / 10,000 animals treated)                             | Injection site infection <sup>1</sup>   |
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Anaphylaxis <sup>2</sup> ;<br>Increased respiratory rate <sup>3</sup> ;<br>Increased heart rate <sup>3</sup> ;<br>Abdominal pain <sup>3</sup> , Diarrhoea <sup>3,5</sup> ;<br>Incoordination <sup>3</sup> ;<br>Lying down <sup>3</sup> ;<br>Retained placenta <sup>4</sup> , Metritis <sup>4</sup> , Dystocia <sup>4</sup> , Stillbirth <sup>4</sup> ;<br>Restlessness, Frequent urination <sup>3,5</sup> ; |

<sup>1</sup> 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.

<sup>2</sup> Requiring immediate medical attention. Can be life-threatening.

<sup>3</sup> Cloprostenol may cause effects similar to prostaglandin F<sub>2α</sub> activity in the smooth muscles.

<sup>4</sup> 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.

<sup>5</sup> In case of occurrence, these effects are observed within 15 minutes post-injection and usually disappear after one hour.

Pigs (sows):

|  |   |
|--|---|
| Rare<br>(1 to 10 animals / 10,000 animals treated)                             | Injection site infection <sup>1</sup>   |
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Anaphylaxis <sup>2</sup> ;<br>Increased respiratory rate <sup>3</sup> ;<br>Increased heart rate <sup>3</sup> ;<br>Abdominal pain <sup>3</sup> , Diarrhoea <sup>3,5</sup> ;<br>Incoordination <sup>3</sup> ;<br>Lying down <sup>3</sup> ;<br>Retained placenta <sup>4</sup> , Metritis <sup>4</sup> , Dystocia <sup>4</sup> , Stillbirth <sup>4</sup> ;<br>Restlessness, Frequent urination <sup>3,5</sup> |

<sup>1</sup> 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.

<sup>2</sup> Requiring immediate medical attention. Can be life-threatening.

<sup>3</sup> Cloprostenol may cause effects similar to prostaglandin F<sub>2α</sub> activity in the smooth muscles.

<sup>4</sup> 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.

<sup>5</sup> 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 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 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.

### **3.8 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.

### **3.9 Administration routes and dosage**

Intramuscular use.

#### Cattle (cows and heifers):

One dose equals 500 micrograms of cloprostenol per animal, corresponding to 5.7 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:

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 5<sup>th</sup> and the 150<sup>th</sup> day of gestation.

#### Pigs (sows):

One dose equals 175 micrograms of cloprostenol per animal, corresponding to 2 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.

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

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.

### **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:

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**

Cloprostenol sodium, a (racemic) analogue of prostaglandin  $F_{2\alpha}$  ( $PGF_{2\alpha}$ ), is a very potent luteolytic agent. It causes functional and morphological regression of the corpus luteum (luteolysis) followed by return to oestrus and normal ovulation.

Furthermore, this group of substances has a contractile effect on the smooth muscles (uterus, gastrointestinal tract, respiratory tract, vascular system).

The veterinary medicinal product does not demonstrate any androgenic, oestrogenic or anti progesterone activity and its effect on pregnancy is due to its luteolytic property.

Unlike other prostaglandin analogues, cloprostenol has no thromboxane  $A_2$  activity and does not cause platelet aggregation.

### **4.3 Pharmacokinetics**

Metabolism studies, using  $15\text{-}^{14}\text{C}$ -cloprostenol have been performed in pigs and cattle (by IM administration) to determine residue levels.

The kinetic studies indicate that the compound is rapidly absorbed from the site of injection, is metabolised then excreted in approximately equal proportion in urine and faeces. In cattle, less than 1% of the administered dose is eliminated via milk. The major route of metabolism appears to be  $\beta$ -oxidation to the tetranor or dinor acids of cloprostenol.

Peak values of radioactivity in blood were observed within 1 hour of a parenteral dose and declined with a  $t_{1/2}$  of between 1 – 3 hours depending on species.

## **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: 2 years.

Shelf life after first opening the immediate packaging: 28 days.

### **5.3 Special precautions for storage**

Do not store above 25°C.

Protect from light.

Keep the vial in the outer carton.

### **5.4 Nature and composition of immediate packaging**

Vial of colourless glass, type I, with a fluorinated bromobutyl stopper and an aluminium cap.

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.

### **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.

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 national collection systems applicable to the veterinary medicinal product concerned.

## **6. NAME OF THE MARKETING AUTHORISATION HOLDER**

Veyx-Pharma GmbH

## **7. MARKETING AUTHORISATION NUMBER(S)**

## **8. DATE OF FIRST AUTHORISATION**

Date of first authorisation:

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

## **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>).



**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

PGF Veyx 0.0875 mg/ml solution for injection for cattle and pigs

**2. STATEMENT OF ACTIVE SUBSTANCES**

1 ml solution contains 0.0875 mg cloprostenol (equivalent to 0.092 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**

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**

**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

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

1 ml solution contains: 0.0875 mg cloprostenol

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 28 days.

Use by: \_\_\_\_\_

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### **1. Name of the veterinary medicinal product**

PGF Veyx 0.0875 mg/ml solution for injection for cattle and pigs

### **2. Composition**

Each ml solution contains 0.0875 mg cloprostenol (equivalent to 0.092 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<sub>2α</sub> 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<sub>2α</sub> 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<sub>2α</sub> 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<br>(1 to 10 animals / 10,000 animals treated)                             | Injection site infection <sup>1</sup>   |
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Anaphylaxis <sup>2</sup> ;<br>Increased respiratory rate <sup>3</sup> ;<br>Increased heart rate <sup>3</sup> ;<br>Abdominal pain <sup>3</sup> , Diarrhoea <sup>3,5</sup> ;<br>Incoordination <sup>3</sup> ;<br>Lying down <sup>3</sup> ;<br>Retained placenta <sup>4</sup> , Metritis <sup>4</sup> , Dystocia <sup>4</sup> , Stillbirth <sup>4</sup> ;<br>Restlessness, Frequent urination <sup>3,5</sup> |

<sup>1</sup> 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.

<sup>2</sup> Requiring immediate medical attention. Can be life-threatening.

<sup>3</sup> Cloprostenol may cause effects similar to prostaglandin F<sub>2α</sub> activity in the smooth muscles.

<sup>4</sup> 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.

<sup>5</sup> In case of occurrence, these effects are observed within 15 minutes post-injection and usually disappear after one hour.

Pigs (sows):

|  |                                       |
|--|---------------------------------------|
| Rare<br>(1 to 10 animals / 10,000 animals treated) | Injection site infection <sup>1</sup> |
|--|---------------------------------------|

|   |   |
|---|---|
| <p>Very rare<br/>(&lt;1 animal / 10,000 animals treated, including isolated reports):</p> | <p>Anaphylaxis<sup>2</sup>;<br/>Increased respiratory rate<sup>3</sup>;<br/>Increased heart rate<sup>3</sup>;<br/>Abdominal pain<sup>3</sup>, Diarrhoea<sup>3,5</sup>;<br/>Incoordination<sup>3</sup>;<br/>Lying down<sup>3</sup>;<br/>Retained placenta<sup>4</sup>, Metritis<sup>4</sup>, Dystocia<sup>4</sup>, Stillbirth<sup>4</sup>;<br/>Restlessness, Frequent urination<sup>3,5</sup>;</p> |
|---|---|

<sup>1</sup> 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.

<sup>2</sup> Requiring immediate medical attention. Can be life-threatening.

<sup>3</sup> Cloprostenol may cause effects similar to prostaglandin F<sub>2α</sub> activity in the smooth muscles.

<sup>4</sup> 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.

<sup>5</sup> 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.

## **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 5.7 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 5<sup>th</sup> and the 150<sup>th</sup> day of gestation.

### Pigs (sows):

One dose equals 175 micrograms of cloprostenol per animal, corresponding to 2 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.

#### **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 or household waste.

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**

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. Date on which the package leaflet was last revised**

DD month YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

**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](mailto:pharmacovigilance@veyx.de)

Manufacturer responsible for batch release:

Veyx Pharma BV  
Forellenweg 16  
NL-4941 SJ Raamsdonksveer  
The Netherlands

Local representatives and contact details to report suspected adverse reactions:

<details to be filled in in the national phase>

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.