1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ALFAGLANDIN C 0.250 mg/ml solution for injection for cattle.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per ml:

Active substance:
Cloprostenol 0.250 mg (as cloprostenol sodium)

Excipient(s):
Chlorocresol 1 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

A clear, practically colourless, watery solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (cows).

4.2 Indications for use, specifying the target species

–Pyometra caused by functional or persisting corpus luteum
–Suboestrus caused by functional or persisting corpus luteum
–Oestrus synchronisation
–Termination of abnormal pregnancy up to day 150 of the pregnancy
–Ovarian luteal cysts
–Induction of parturition

4.3 Contraindications

Do not use in pregnant animals where the induction of abortion or parturition is not intended. Do not use in case of bronchospasms or spastic diseases of the gastrointestinal tract.

4.4 Special warnings for each target species

A refractory period of 4 to 5 days after ovulating has to be taken into account during which cattle will not be sensitive to the luteolytic effects of prostaglandins.

4.5 Special precautions for use

Special precautions for use in animals

Administer by intramuscular injection observing the usual aseptic precautions.
To reduce the risk of anaerobic infections care should be taken to avoid injection through wet or dirty areas of skin.

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

-Prostaglandins of the F2α type can be absorbed through the skin and may cause bronchospasm or miscarriage.
-Direct contact with the skin or eyes may cause irritation and allergic reactions.
-The product should not be administered by pregnant women or women who are intending to become pregnant.
-People with a known hypersensitivity to cloprostenol or chlorocresol should avoid contact with the veterinary medicinal product.
-This product can be absorbed through the skin and therefore care should be taken when handling the product, especially by women of child-bearing potential, asthmatics and people with bronchial and other respiratory problems.
-Avoid direct contact with the skin and eyes.
-Avoid accidental self-injection
-Wear gloves.
-Accidental spillage on the skin or into the eyes should be washed off immediately with plenty of water.
-In case of accidental self-injection or respiratory problems, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Localised post-injection bacterial infections, which may become generalised, are occasionally reported if anaerobic bacteria are introduced into the tissue by the injection. When used for induction of parturition, the incidence of retained placenta may be increased, depending on the time of treatment.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not administer during pregnancy, unless the objective is to induce termination of an abnormal pregnancy or to induce parturition.

Fertility:
The product has no negative influence on fertility. No negative effects on offspring have been reported after insemination or natural service after treatment with cloprostenol.

4.8 Interaction with other medicinal products and other forms of interaction

Simultaneous use of oxytocin and cloprostenol increases the effect on contractility of the musculature of the uterus. Synthesis of endogenous prostaglandins is inhibited in animals treated with non-steroidal anti-inflammatory drugs.

4.9 Amounts to be administered and administration route

By intramuscular injection: 0.5 mg (2 ml) cloprostenol per animal.
Oestrus synchronisation: two injections with 11 days interval.
Termination of abnormal pregnancy: between day 5 and 150 after insemination.
Induction of parturition: within 10 days before the expected date of parturition.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The product has a wide safety margin with overdoses of up to ten-fold the recommended dose generally being well-tolerated. Large overdoses (50-200 times the recommended dose) may cause nausea and vomiting, increased defecation and urination, increased rectal temperature, increased respiratory rate, bronchoconstriction, and increased heart rate. There is no antidote available.

4.11 Withdrawal period(s)

Meat and offal: 1 day
Milk: zero hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Prostaglandins

ATCvet code: QG02AD90

5.1 Pharmacodynamic properties

Cloprostenol is a synthetic prostaglandin analogue structurally related to Prostaglandin F2α. It is a potent luteolytic agent for use in cattle. Cloprostenol causes functional and morphological regression of the corpus luteum (luteolysis) followed by return to oestrus and normal ovulation.

5.2 Pharmacokinetic particulars

After intramuscular injections of the product in cows the following pharmacokinetic parameters were found: a Cmax at 16 min. and a T1/2 of 44 min. These parameters indicate a rapid absorption from the injection site and also a rapid elimination. After intramuscular administration of 0.5 mg and 10 mg (C14) cloprostenol to cows the excretion by urine was 58% and 56% of the doses respectively. Unchanged cloprostenol and tetranor acid were the main metabolites found in the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Sodium citrate
Citric acid
Chlorocresol
Sodium hydroxide (for pH adjustment)
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.
Incompatible with strong acidic/alkaline products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Protect from light. Protect from frost.
Store below 25°C after first opening the immediate packaging.

6.5 Nature and composition of immediate packaging

Amber glass, 20 ml, type II vial with bromobutyl rubber stopper and aluminium closure; one vial in a carton box or 28 vials in a polystyrene box.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

7 MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V
Kuipersweg 9
3449 JA Woerden
Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10980/012/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th June 2011
Date of last renewal: 18th April 2013

10 DATE OF REVISION OF THE TEXT

March 2018