Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Prosolvin 7.5 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:
Luprostiol7.5 mg (0.75 % w/v)

Excipients:
For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, pigs and horses.

4.2 Indications for use, specifying the target species

*Oestrus control:*cows and heifers treated during the luteal phase will normally return to oestrus and ovulate 2-4 days after treatment.In mares oestrus will normally occur within 5 days of treatment followed by ovulation 2-4 days later.

Oestrus synchronisation: when a group of cows at different stages in the oestrus cycle are to be synchronised, two injections of Prosolvin will be required with an interval of 10-12 days between injections.It is recommended that animals be serviced/inseminated at the oestrus following treatment, i.e. at 72 hours after the second injection.If doubleinsemination is preferred, this should take place at 72 and 96 hours after the second injection.

*Treatment of sub-oestrus:*this condition is found in lactating cows at the peak of production. Animals may have normal cyclical ovarian activity, but may not show any outward signs of oestrus.Having confirmed the presence of a corpus luteum, treatment with Prosolvin will cause luteal regression followed by oestrus in 2-4 days.

Induction of abortion: Prosolvin can be used to induce abortion in cattle and mares.Animals may be treated from 1 week and up to 5 months after misalliance.Following luteal regression abortion will usually occur within 7 days.In some cases, particularly those later on the pregnancy, a second or third treatment may be required.

*Induction of parturition:*in cattle Prosolvin may be used to initiate labour after the 270th day of pregnancy.Calving may be expected within 3 days of treatment. In pigs, Prosolvin may also be used on or after the 111th day of the gestation period.Parturition will normally follow within 48 hours.Prosolvin may also be used to induce parturition in the mare.Treatment must occur on or after the 330th day of pregnancy and the mare must show relaxed pelvic ligaments and functional udder with colostrum.Following treatment parturition may be expected within a few hours.

Treatment of anoestrus: a persistent corpus luteum, particularly during lactation may result in an anoestral mare.Prosolvin may be used to cause luteal regression; oestrus and ovulation will then follow usually within 4-8 days of treatment.

4.3 Contraindications

This product should not be given to pregnant animals unless the intention is to induce abortion or parturition.
Do not use in animals known to be hypersensitive to the active ingredient.

4.4 Special warnings for each target species

There is a refractory period of about 4-5 days post ovulation when animals will not respond to treatment.The length of the gestation period in pigs can vary depending on breed.Prosolvin should not be given more than 3 days before the expected parturition date.There is a risk of reduced piglet viability if parturition is induced earlier than 72 hours before the predicted farrowing date.Early induction of parturition in cattle may result in a higher than normal incidence of retained foetal membranes.

4.5 Special precautions for use

Special precaution(s) for use in animals
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Prostaglandins of the $F_2\alpha$ type can be absorbed through the skin and may cause bronchospasm or miscarriage.
Care should be taken when handling the product to avoid self-injection or skin contact.

Women of child-bearing age, asthmatics and persons with bronchial or other respiratory problems should avoid contact with, or wear disposable plastic gloves when administering the product.
The product should not be administered by pregnant women.
Accidental spillage on the skin should be washed off immediately with soap and water.

4.6 Adverse reactions (frequency and seriousness)

Very few adverse reactions have been seen with Prosolvin. Sweating and a slight respiratory effect have been reported in a small number of horses but these effects were mild and transient.It is, however, possible for prostaglandins to cause diarrhoea in horses and abdominal discomfort in cattle.

4.7 Use during pregnancy, lactation or lay

This product should not be given to pregnant animals unless the intention is to induce abortion or parturition.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Cows: single or repeated injections of 2ml (15mg luprostiol)
Heifers: single or repeated injections of 1ml (7.5mg luprostiol)
Horses: single or repeated injections of 1ml (7.5mg luprostiol)
Pigs: single injections of 1ml (7.5mg luprostiol)

Prosolvin is administered by deep intramuscular injection.

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

No specific treatment or antidote recommended.

4.11 Withdrawal period(s)

Meat and offal: 24 hours.
Milk: zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: genito urinary system and sex hormones, prostaglandins, luprostiol

ATC vet code: QG02AD91

Prosolvin is a luteolytic agent. Provided an active corpus luteum is present, it will cause luteal regression which will be followed by follicle growth, oestrus and ovulation.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Hydroxide
Water for Injections
Propylene Glycol

6.2 Major incompatibilities

None known but product should not be mixed with other products.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years
Shelf life after first opening the immediate container: 28 days.

6.4 Special precautions for storage

Store in the original container. Protect from light.

6.5 Nature and composition of immediate packaging

Clear, glass Type I (Ph. Eur.) vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap, containing 2 ml, 10ml and 20 ml of product.
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

Virbac S.A.
1ère avenue
2065 M LID
06516 Carros
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10988/078/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 November 2008
Date of last renewal: 30 September 2009

10 DATE OF REVISION OF THE TEXT

September 2009