PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box of 10ml or 20ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prosolvin Luprostiol 7.5 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance
Luprostiol 7.5 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

10 ml or 20 ml.

5. TARGET SPECIES

Cattle, pigs and horses. For administration to cattle, pigs and horses by intramuscular injection.

6. INDICATIONS

Reproduction

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read package leaflet for directions, disposal advice and warnings before use.

AVOID SELF-INJECTION OR SKIN CONTACT.

8. WITHDRAWAL PERIOD

Withdrawal periods:
Meat (cattle and pigs) - 4 days
Milk (cattle) - 12 hours
Not to be used in horses intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

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10. EXPIRY DATE

Exp. : xxxxxxx

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light. Following withdrawal of the first dose, use within 28 days. Keep container in outer carton. Discard unused material.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF

For animal treatment only.

POM-V

U.K. authorised veterinary medicinal product

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:
Virbac
06516 Carros Cedex
France

Distributor:
Virbac Ltd – Suffolk IP30 9UP – U.K.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4158

17. MANUFACTURER'S BATCH NUMBER

BN: xxxxx
Exp.: xxxxxxx

SMALL IMMEDIATE PACKAGING UNITS

Vial label of 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prosolvin luprostiol 7.5 mg/ml solution for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Luprostiol 7.5 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

4. ROUTE(S) OF ADMINISTRATION

Solution for injection.

For administration to cattle, pigs and horses.

Read package leaflet for directions, disposal advice and warnings before use.

5. WITHDRAWAL PERIOD

Withdrawal periods:
Meat (cattle, pigs) - 4 days / Milk (cattle) - 12 hours

Do not store above 25°C. Protect from light. Once broached use entire contents within 28 days. Discard unused material.

Vm 05653/4158
Keep container in outer carton.

POM-V

To be supplied only on veterinary prescription.
Keep out of reach and sight of children.

MA Holder:

Virbac
06516 Carros Cedex
France

Distributor:
Virbac Ltd – Suffolk IP30 9UP – U.K.

6. BATCH NUMBER

BN:

7. EXPIRY DATE

Exp:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

SMALL IMMEDIATE PACKAGING UNITS

Vial label of 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prosolvin luprostiol 7.5 mg/ml solution for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Luprostiol 7.5 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml

4. ROUTE(S) OF ADMINISTRATION

Solution for injection.

For administration to cattle, pigs and horses.

Read package leaflet for directions, disposal advice and warnings before use.

5. WITHDRAWAL PERIOD

Withdrawal periods:
Meat (cattle, pigs) - 4 days / Milk (cattle) - 12 hours

Do not store above 25°C. Protect from light. Once broached use entire contents within 28 days. Discard unused material.

Vm 05653/4158
Keep container in outer carton.

POM-V

To be supplied only on veterinary prescription.
Keep out of reach and sight of children.

MA Holder:

Virbac
06516 Carros Cedex
France

Distributor:
Virbac Ltd – Suffolk IP30 9UP – U.K.

6. BATCH NUMBER

BN:

7. EXPIRY DATE

Exp:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

SMALL IMMEDIATE PACKAGING UNITS

Box and vial label of 2 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prosolvin 7.5 mg/ml solution for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Luprostiol 7.5 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

2 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

Cattle: 4 days
Milk: 12 hours
Pigs – meat: 4 days
Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

Exp:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

POM-V

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Virbac
1ère Avenue, 2065 m – LID
06516 Carros
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prosolvin 7.5 mg/ml solution for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Active substance
Luprostiol 7.5 mg
PRESENTATION
A clear, slightly viscous solution for injection containing 7.5 mg/ml Luprostiol, a synthetic analogue of Prostaglandin $F_{2\alpha}$ in propylene glycol/water.

4. INDICATION(S)

4. INDICATION(S) USES

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. PROSOLVIN is indicated for use in cattle, pigs and horses in the following situations:

1. *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.

2. *Oestrus synchronisation:* when a group of cows at different stages in the oestrous 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 double insemination is preferred, this should take place at 72 and 96 hours after the second injection. Alternatively PROSOLVIN may be used in conjunction with GnRH (see Further information).

3. *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.

4. *Induction of abortion:* PROSOLVIN can be used to induce abortion in cattle and mares. Animals may be treated from 1 week up to 5 months after mesalliance. 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.

5. *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 be used on or after the 113th day of the gestation period (see also Further information). 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 a functional udder with colostrum. Following treatment parturition may be expected within a few hours.

6. *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.

7. *Treatment of endometritis or pyometra in cows*: the luteolytic effect of PROSOLVIN induces oestrus which will aid the expulsion of uterine discharge. A single injection of 2 ml should be given; intransigent cases may require a repeat treatment after 10-14 days or alternative therapies should be considered.

5. CONTRA-INDICATIONS, WARNINGS, ETC.

1. This product should not be given to pregnant animals unless the intention is to produce abortion or parturition.
2. Intravenous injection is not recommended.
3. 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.

Operator warning: 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.
Accidental spillage on the skin should be washed off immediately with soap and water.

6. ADVERSE REACTIONS

Very few adverse reactions have been seen with this product. 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.

7. TARGET SPECIES

Cattle, pigs and horses.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Cows: single or repeated injections of 2 ml (15 mg luprostiol)
Heifers: single or repeated injections of 1 ml (7.5 mg luprostiol)
Horses: single or repeated injections of 1 ml (7.5 mg luprostiol)
Pigs: single injections of 1 ml (7.5 mg luprostiol)
PROSOLVIN is administered by deep intramuscular injection.

9. ADVICE ON CORRECT ADMINISTRATION

The product is administered by deep intramuscular injection.

10. WITHDRAWAL PERIOD(S)

10. WITHDRAWAL PERIOD(S)

Animals must not be slaughtered for human consumption during treatment.
Cattle and pigs may be slaughtered for human consumption only after 4 days from the last treatment. Milk from treated cattle may be taken for human consumption 12 hours after the last treatment. Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

11. SPECIAL STORAGE PRECAUTIONS

PHARMACEUTICAL PRECAUTIONS

Do not store above 25°C. Protect from light. Following withdrawal of the first dose, use the product within 28 days. Discard unused material. When the container is broached for the first time, the date on which any product remaining in the container should be discarded should be calculated. A statement of the in-use shelf life of the product is given on the package insert. This discard date should be written in the space provided on the label. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. Keep container in outer carton.

12. SPECIAL WARNING(S)

Special warning for each target species

FURTHER INFORMATION

There is a refractory period 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 2 days before the expected parturition date. There is a risk of reduced piglet viability if parturition is induced earlier than 48 hours before the predicted farrowing date. Early induction of parturition in cattle may result in a higher than normal incidence of retained foetal membranes. When prostaglandins are used in

the treatment of endometritis in cattle, adjunct therapy may be of benefit in certain cases.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

03/2012

15. OTHER INFORMATION

Not all presentations may be marketed.

PROSOLVIN can be used as part of a 10-day GnRH/prostaglandin/GnRH oestrus synchronisation and insemination regime to increase submission rates and significantly reduce the calving to conception interval. The use of GnRH 7 days prior to PROSOLVIN increases the proportion of cows able to respond to the prostaglandin and co-ordinates a new follicular wave so more cows will ovulate during a shorter time after PROSOLVIN. A second GnRH treatment after the prostaglandin further tightens synchrony of ovulation in relation to the service time.
The GnRH/prostaglandin/GnRH regime for breeding dairy cows at a preplanned time without the need for specific heat detection is summarised below:

Day 0	GnRH (2.5 ml)	
Day 7	Prosolvin (2 ml)	
Day 9	GnRH (2.5 ml)	54-56 hours post prostaglandin or at AI if sooner
Day 10	AI	72 hours post prostaglandin or at observed heat if sooner.

When using the fixed time insemination regime, it is recommended that cows showing signs of oestrus after prostaglandin treatment should be inseminated when observed in oestrus rather than completing the synchronisation programme.
Trials have shown that for cows holding to their first service, use of GnRH/prostaglandin/GnRH regime can improve the calving to conception interval by 11 days when compared to controls. When including all services, the calving to conception interval was shown to be improved by 7 days. Initial trial work indicates that this system is not suitable for heifers.

For animal treatment only.
Keep out of reach and sight of children.

LEGAL CATEGORY

POM-V

U.K. authorised veterinary medicinal product

To be supplied only on veterinary prescription.

PACKAGE QUANTITIES
Multidose vials containing 10 ml and 20 ml.

MARKETING AUTHORISATION NUMBER
Vm 05653/4158

DATE OF PREPARATION
October 2008

Distributor:
Virbac Ltd – Windmill Avenue – Woolpit Business Park – Woolpit – Bury SQt Edmunds – Suffolk IP30 9UP – United Kingdom

Approved: 08/08/2017