LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 10 vials of 5 ml
Cardboard box of 5 vials of 10 ml
Cardboard box of 1 vial of 30 ml
Cardboard box of 1 vial of 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enzaprost 5 mg/ml Solution for injection for cattle and pig
dinoprost

2. STATEMENT OF ACTIVE SUBSTANCES

Dinoprost (as trometamol): 5 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

10 x 5 ml
5 x 10 ml
30 ml
50 ml

5. TARGET SPECIES

Cattle
Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle:
Meat and offal: 2 days
Milk: zero hours
Pigs:
Meat and offal: 2 days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP:
Once broached, use within 14 days, by: __/__/__

11. SPECIAL STORAGE CONDITIONS

After first broaching the vial, do not store above 25° C.

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

Disposal: read package leaflet.

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

For animal treatment only - To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4015

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 5 ml/ Vial of 10 ml/ Vial of 30 ml/ Vial of 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enzaprost 5 mg/ml Solution for injection for cattle and pig
dinoprost

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Dinoprost (as trometamol) 5 mg/ml

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

5 ml
10 ml
30 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle:
Meat and offal: 2 days - Milk: zero hours
Pigs:
Meat and offal: 2 days

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP:
Once broached, use within 14 days, by: __/__/__

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Enzaprost 5 mg/ml Solution for injection for cattle and pig

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

Marketing authorisation holder:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:
Ceva Santé Animale, 10 av. de La Ballastière, 33500 Libourne, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enzaprost 5 mg/ml Solution for injection for cattle and pig
dinoprost

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

Each ml contains:
Active substance:
Dinoprost (as trometamol) .....5 mg
Excipients:
Benzyl alcohol (E1519) ..... 16.5 mg

4. INDICATION(S)

The product is indicated for its luteolytic effects in cattle and pigs.

Cattle
The luteolytic effect of the product can be exerted in the following therapeutic uses:
1. Oestrus synchronisation.
2. Treatment of sub-oestrus or silent heat in cows which have a functional corpus luteum, but do not express behavioural oestrus.
3. Induction of abortion until day 120 of pregnancy.
4. Induction of parturition.
5. As an aid in the treatment of chronic metritis or pyometra where there is a functional or persistant corpus luteum.

Pigs
1. Induction of parturition from day 111 of pregnancy.
2. Post partum use: reduction of the weaning to oestrus interval (WOI) and the weaning to fertile service interval (WFSI) in sows with puerperal problems such as metritis in herds with reproductive problems.

5. CONTRAINDICATIONS

Do not treat animals if they suffer from either acute or subacute disorders of the vascular system, gastro-intestinal tract or respiratory system.
Do not administer to pregnant animals, unless it is desirable to induce parturition or interruption of pregnancy.
Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Cattle
Increased rectal temperature (hyperthermia) has been reported very rarely. However, rectal temperature changes have been transient in all cases observed and have not been detrimental to the animal. Limited salivation has been seen in some instances.
The side-effects disappear within one hour after the administration of PGF2α.
In cattle, if used for induction of parturition, retained foetal membranes may occur more frequently, depending on the time of use of the product.

Pigs
Transient side-effects consisting of increased body temperature, signs of pain at the site of injection increased respiratory rate, increased salivation, stimulation of defecation and urination, flushing of skin, dyspnea, slight ataxia, abdominal muscle spasms and vomiting occur occasionally following the administration of dinoprost in pregnant sows and gilts. These effects tend to parallel the signs exhibited by sows prior to normal parturition, only they appear to be condensed in time. These effects are usually seen within 10 minutes of injection and disappear within 3 hours.
Nest building is a common behaviour 5 to 10 minutes after the administration of prostaglandin in sows that are housed in pen or pasture.
In very rare occasions, anaphylactic-type reactions, hyperactivity (restlessness - arching of back, pawing, and rubbing and gnawing the crate) and pruritus have been reported.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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 already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively you can report via your national reporting system.

7. TARGET SPECIES

Cattle: cows, heifers.
Pigs: sows, gilts.

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

Intramuscular use.

Cattle
1. Oestrus synchronisation:
One administration of 25 mg of dinoprost (as trometamol), ie 5 ml of the product per animal, to be repeated, if necessary after 11 (10 to 12) days.
Animals treated during dioestrus will normally return to oestrus and ovulate within two to four days after treatment.
Animals treated with the product may be bred by natural service, artificial insemination on detected oestrus or at fixed time insemination (72 and 96 hours after the second injection is usually recommended).

2. Treatment of sub-oestrus or silent heat in cows which have a functional corpus luteum, but do not express behavioural oestrus:
One administration of 25 mg of dinoprost (as trometamol), ie 5 ml of the product per animal, to be repeated, if necessary after 11 (10 to 12) days.

3. Induction of abortion until day 120 of pregnancy:
One administration of 25 mg of dinoprost (as trometamol), ie 5 ml of the product per animal.
The product may be used to terminate pregnancy in cattle until day 120 of pregnancy through its luteolytic effect.

4. Induction of parturition:
One administration of 25 mg of dinoprost (as trometamol), ie 5 ml of the product per animal on or after day 270 of gestation.
The interval from administration to parturition is one to eight days (average three days).

5. For the aid in the treatment of chronic metritis or pyometra where there is a functional or persistent corpus luteum:
One administration of 25 mg of dinoprost (as trometamol), ie 5 ml of the product per animal, to be repeated, if necessary after 11 (10 to 12) days.

Pigs
To avoid excessive broaching of the stopper when treating large numbers of animals using the 50 ml pack size, the use of a multiple dose syringe with a draw-off needle is recommended.
1. Induction of parturition from day 111 of pregnancy:
One administration of 10 mg of dinoprost (as trometamol), ie 2 ml of the product per animal within 3 days of expected parturition.

Response to treatment by individual animals varies within a range of 24-36 hours from administration to parturition. This can be used to control the time of farrowing in sows and gilts in late gestation. Treatment earlier than 3 days prior to predicted farrowing date may induce weak piglets.

2. Post-partum use:
One administration of 10 mg of dinoprost (as trometamol), ie 2 ml of the product per animal 24 to 36 hours after parturition.

9. ADVICE ON CORRECT ADMINISTRATION

Full aseptic precautions should be taken. Use a sterile syringe and needle and make the injection through an area of clean skin. Care should be taken to avoid injection through wet or dirty areas of skin.

10. WITHDRAWAL PERIOD(S)

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

Pigs:
Meat and offal: 2 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Shelf-life after first broaching the vial: 14 days
After first broaching the vial, do not store above 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special warnings for each target species:
The product is ineffective when administered prior to day 5 after ovulation.

Special precautions for use in animals:
Localised post injection bacterial infections that may become generalised have been reported. 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 post injection bacterial infections.
Do not administer by intravenous route.
Induction of abortion or parturition by using exogenous substances may increase the risk for dystocia, fetal mortality, retention of the placenta and/or metritis.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Prostaglandins of the PGF2α 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.
Accidental spillage on the skin, or accidental eye contact should be washed off immediately with clean water.
Impervious gloves should be worn to avoid skin contact.
Accidental injection may be a particular hazard to women who are pregnant, intending to become pregnant, or whose pregnancy status is unknown and to asthmatics and persons with bronchial or other respiratory problems.
Asthmatics and persons with bronchial or other respiratory problems should handle the product with care to avoid accidental self-injection and skin contact.
Pregnant women, women of child-bearing age, asthmatics and persons with bronchial and other respiratory problems should not use the product or should wear disposable plastic gloves

Pregnancy and lactation:
Pregnancy status should be determined prior to injection since Dinoprost has been demonstrated to result in abortion or parturition induction when administered at sufficiently high doses in many animal species.
If pregnant, the unlikely possibility of uterine rupture should be borne in mind, especially if cervical dilation does not occur.
Induction of parturition in pigs earlier than 72 hours prior to predicted farrowing date may result in reduced piglet viability.

Interaction with other medicinal products and other forms of interaction:
As non-steroidal anti-inflammatory drugs may inhibit the endogenous prostaglandin synthesis, concomitant administration of these compounds with the product may decrease the luteolytic effects.
As oxytocics stimulate the production of prostaglandins, concomitant administration of these compounds with the product, may exacerbate the luteolytic effects.

Overdose (symptoms, emergency procedures, antidotes):
Increased rectal temperature and a slight transitory increase in heart rate can be observed at 5 or 10 times the recommended dosage in cows and heifers.

Incompatibilities:
In absence of compatibilities studies do not mix with other veterinary medicinal products.

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

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

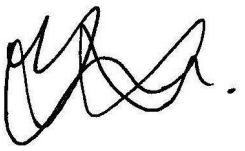
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2022

15. OTHER INFORMATION

Pack sizes:
Cardboard box of 10 vials of 5 ml
Cardboard box of 5 vials of 10 ml
Cardboard box of 1 vial of 30 ml
Cardboard box of 1 vial of 50 ml

Not all pack sizes may be marketed.



Approved: 22 September 2022