

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroprost 0.5 % w/v Solution for Injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Each ml of product contains 5 mg (0.5% w/v) of Dinoprost (Prostaglandin F_{2α}),

Excipients:

2.5 mg (0.25% w/v) Phenol as antimicrobial preservative.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.

Clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

Noroprost is indicated for its luteolytic effect on corpora lutea in cattle. This luteolytic action of Noroprost may be utilised as follows:

1. To improve control of the time of oestrus in cycling cattle.
2. To control breeding in cattle.
3. To induce parturition in cattle.
4. Synchronisation of recipient cattle for embryo transplantation.
5. To induce abortion in cattle.
6. To treat cattle which have a functional corpus luteum but do not express behavioural oestrus (sub-oestrus or silent heat).
7. For treatment of chronic metritis and pyometra in cattle.
8. For treatment of ovarian luteal cysts.

4.3 Contraindications

Do not administer by the intravenous route.

Animals should not be treated if they suffer from either acute or sub acute disorders of the vascular system, gastrointestinal tract or respiratory system.

4.4 Special Warnings for each target species

No special warnings.

4.5 Special precautions for use

Special precautions for use in animals

Noroprost is ineffective when administered prior to day 5 after ovulation.

Observe aseptic precautions during use.

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.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Side-effects are infrequently observed and are of a transitory nature as the compound is rapidly metabolised in the tissues.

In cattle, salivation, tremor, restlessness and mild diarrhoea can occur for 15 - 30 minutes. The side-effects disappear within one hour after the administration of $PGF_{2\alpha}$.

4.7 Use during pregnancy, lactation or lay

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 to cattle.

If pregnant the unlikely possibility of uterine rupture should be borne in mind, especially if cervical dilation does not occur.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Administer by intramuscular injection.

A single injection is usually sufficient, but on occasions where a response is not observed, a second administration of 5 ml Noroprost may be administered 10-12 days after the first injection.

Oestrus control)	
Controlled breeding)	
Induction of parturition)	
Induction of abortion)	25 mg (5 ml)
Treatment of sub-oestrus)	
Treatment of metritis/pyometra)	
Treatment of ovarian luteal cysts)	

Embryo Transplantation - Two 5 ml (25 mg) injections given at an interval of 10 - 12 days.

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

Not applicable.

4.11 Withdrawal period

Milk – Zero hours.

Meat – 1 day

Animals must not be slaughtered for human consumption during treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Dinoprost

ATC Vet Code: QG02AD01

5.1 Pharmacodynamic properties

Dinoprost is the synthetically produced nature-identical prostaglandin (PGF_{2α}). It is a natural luteolytic hormone and is also involved in uterine contraction at the time of parturition. The luteolytic action of PGF_{2α} is used to control the oestrus cycle in dairy cattle and therefore it is a useful aid in the management and treatment of reproductive conditions in dairy cattle.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol
Sodium Acetate Trihydrate
Sodium Hydroxide (for pH adjustment)
Water

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale : 2 Years.
Shelf life after first opening the immediate packaging : 21 days.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.
Following withdrawal of the first dose, use the product within 21 days.
Discard unused material.

6.5 Nature and composition of immediate packaging

10 ml and 30 ml clear Type II glass vials and closed with bromobutyl bungs and aluminium overseals.
Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works,
Camlough Road
NEWRY
Co. Down, BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBERS

Vm 02000/4110

9. DATE OF FIRST AUTHORISATION

9th January 1996

10. DATE OF REVISION OF THE TEXT

December 2008