SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NORFENICOL 300 MG/ML INJECTION VETERINARY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Florfenicol 300 mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
A light yellow to straw coloured solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

Treatment of bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*, *Pasteurella multocida* and *Haemophilus somnus*.

4.3 Contraindications

Do not use in adult bulls intended for breeding purposes.
Do not use in the case of known hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

The product should be used in conjunction with susceptibility testing and take into account official and local antimicrobial policies.

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

People with known hypersensitivity to Florfenicol or any of the excipients should avoid contact with the veterinary medicinal product. In case of accidental contact with skin or eyes, rinse immediately with plenty of water.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

A decrease in food consumption and transient softening of the faeces may occur during the treatment period. The treated animals recover quickly and completely upon termination of treatment.

Intramuscular administration may cause inflammatory lesions at the injection site which may persist for 14 days.

In very rare cases, anaphylactic shock has been reported.

Reporting suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals have not revealed any evidence of teratogenic or foetotoxic effects. However, the effect of florfenicol on bovine reproductive performance and pregnancy has not been assessed. Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

No data available.

4.9 Amounts to be administered and administration route

Swab septum before removing each dose. Use a dry sterile needle and syringe.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
The vials should not be broached more than 20 times. User should therefore select the most appropriate vial size according to the target species to be treated.
When treating groups of animals at the same time, use of a draw-off needle in the vial stopper is recommended to avoid excess stopper broaching. The draw-off needle should be removed after treatment.

For treatment
Intramuscular use: 20 mg/kg bodyweight (1 ml/15 kg) to be administered twice 48 hours apart using a 16-gauge needle.
The dose volume given at any one injection site should not exceed 10 ml.
The injection should only be given in the neck.

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

No symptoms other than those described in section 4.6.

4.11 Withdrawal periods

Meat and offal
39 days.

Milk
Not authorised for use in animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial for systemic use: Amphenicols.
ATC vet code: QJ01BA90

5.1 Pharmacodynamic properties

Florfenicol is a synthetic broad spectrum antibiotic effective against most Gram-positive and Gram-negative bacteria isolated from domestic animals. Florfenicol acts by inhibiting protein synthesis at the ribosomal level and is bacteriostatic. Laboratory tests have shown that florfenicol is active against the most commonly isolated bacterial pathogens involved in bovine respiratory disease which include *Pasteurella haemolytica, Pasteurella multocida,* and *Haemophilus somnus.*

Florfenicol is considered to be a bacteriostatic agent, but *in vitro* studies of florfenicol demonstrate bactericidal activity against *Pasteurella haemolytica, Pasteurella multocida* and *Haemophilus somnus*.

5.2 Pharmacokinetic particulars

Intramuscular administration at the recommended dose of 20 mg/kg maintains efficacious blood levels in cattle for 48 hours. Maximum mean serum concentration (C_{max}) of 3.37 µg/ml occurs at 3.3 hours (t_{max}) after dosing. The mean serum concentration 24 hours after dosing was 0.77 µg/ml.

The harmonic mean elimination half-life was 18.3 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

2-pyrollidone
Glycerol Formal

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Store below 25 °C.
Protect from light.
Keep container in
outer carton

6.5 Nature and composition of immediate packaging

50, 100, 250 and 500 ml clear Type I glass vials and HDPE bottles closed with bromobutyl bungs and aluminium seals.

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 product should be disposed of as toxic waste, do not throw to sewer.

7. MANUFACTURER

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

8. LICENSE HOLDER

Habnayah St. 12, Industrial area Har Tov “A”
Beit Shemesh
ISRAEL

9. LICENSE NUMBER

156-36-33822-00

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