An authorized leaflet approved by The Ministry of Health: June 2016
Consumer leaflet of veterinary product
Veterinarian prescription only medicine
Animal use only

1. Name of veterinary product, route & strength
Norfenicol 300 mg/ml Injection Veterinary
Solution for I.M. injection

2. Active ingredients
Florfenicol 300 mg/ml
Full excepients list is provided under section 13

3. What is the medicine indicated for
Therapeutic classification: Antibiotics
The medicine is indicated for the treatment of bovine respiratory disease (BRD) associated with pasteurella haemolytica, pasteurella multocida and haemophilus somnus.

4. Contra-indications
- Do not use in adult bulls or boars intended for breeding purposes.
- Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
- Do not use in cases of known resistance.
- Not permitted for use in lactating animals producing milk for human consumption.

5. Side effects:
- The medicine may cause inflammatory lesions (swelling and hardness) at the injection site which may persist for 31 days.
- A decrease in food consumption and transient softening of the feces may occur during the treatment period.

The treated animals recover quickly and completely upon termination of treatment.

- In very rare cases, anaphylactic shock has been reported.

Any suspected adverse events should be reported to the Ministry of Health by clicking on the link below and using an online form http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh. gov.il

The form can be found on the Ministry of Health website (www.health.gov.il)

6. Target species
Cattle

7. Route and dose for each target species

Intramuscular Injection:
20 mg/kg body weight (1 ml/15 kg) to be administered twice 48 hours apart.
The dose volume given at any one injection site should not exceed 10 ml.

8. Administration method
It is recommended to use a 16-gauge needle.
The injection should only be given in the neck.
It is recommended to treat animals in the early stages of disease and to evaluate the response to treatment within 48 hours after the second injection.
If clinical signs of respiratory disease persist 48 hours after the last injection, treatment should be changed using another product.
To ensure administration of a correct dose, body weight should be determined as accurately as possible.
Swab septum before removing each dose.
Use a dry sterile needle and syringe.
Do not broach the vial more than 25 times.

9. Withdrawal time:
Meat: 39 days
Milk: Not permitted for use in lactating animals producing milk for human consumption.

10. Special warnings
- Special precautions on target species

Use a suitable draw-off needle or automatic dosing syringe to avoid excessive puncturing of the closure.

Florfenicol should be used for treatment of severe infections only. Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Official national and regional antimicrobial policies should be taken into account when the product is used.

Use of the product deviating from the instructions given in this leaflet may increase the prevalence of bacteria resistant to the Florfenicol and may decrease the effectiveness of treatment with other antimicrobials (e.g. Ceftiofur) due to the potential for cross-resistance.

- User warnings

Do not use the product in known cases of sensitivity to the active substance or to any of the excipients.
Care should be taken to avoid accidental self-injection.

- Pregnancy

Studies in laboratory animals have not revealed any evidence of embryo- or foeto-toxic effects for florfenicol. However, safety during pregnancy and lactation has not been investigated in the target species. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

- Incompatibilities

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

11. Storage conditions
- Prevent intoxication! This medicine and any other medicine should be kept out of the reach and sight of children.
- Do not use after the expiry date stated on the label. Expiry date refers to the last day of the month.
- Store below 25°C. Protect from light. Keep container in the protective sleeve/outer carton.
- Shelf-life after first opening the immediate packaging: 28 days

12. Special precautions for the disposal of unused product or waste materials
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed as toxic waste, do not through into sewage.

13. Additional information
- In addition to the active ingredients, the medicine contains Glycerol Formal and 2-Pyrrolidone
- Package Information
A light yellow to straw color solution.

Available in 50, 100, 250 and 500 ml clear type I glass vials and HDPE plastic vials with bromobutyl rubber bungs and aluminum seal.

50 ml clear type I glass vials as well as the 50 ml, 100ml, 250 ml and 500 ml HDPE plastic vials are presented in a cardboard box.
100 ml, 250 ml and 500 ml glass vials are accompanied by a protective sleeve.

Not all pack sizes may be marketed.
- Registration Authorization Holder: Comex Ltd., P.O.B. 19943,Habnayah St. 12, Industrial Area Har Tov “A”,Bet Shemesh
- Manufacturer: Norbrook Laboratories Limited,
Station Works, Newry, Co. Down,
BT35 6JP, Northern Ireland, UK