CONSUMER PACKAGE INSERT FOR A VETERINARY PRODUCT

This medicine is only dispensed with a veterinarian's prescription

For veterinary use only

1. **Name of the veterinary medicinal product, its form and strength**

   Nuflor veterinary

   A solution for injection for cattle and sheep

2. **Active ingredient(s)**

   Each 1 ml contains the active ingredient**:** Florfenicol - 300 mg

   A list of excipients is detailed in section 13 – "Further information".

3. **What is the medicine intended for**

   Cattle: For treatment of respiratory diseases (BRD) caused by *Mannheimia haemolytica, Pasteurella multocida* and *Haemophilus somnus*.

   Sheep: For treatment of respiratory tract infections caused by *Mannheimia haemolytica* and *Pasteurella multocida* susceptible to florfenicol.

   Therapeutic group:

   Florfenicol is a broad spectrum antibiotic

4. **Contraindications:**

   Do not use in adult bulls and rams intended for breeding purposes.

   Do not use in the case of known hypersensitivity to the active ingredient or to any of the excipients.

5. **Adverse reactions**

   - Cattle: 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. Administration by intramuscular injection may cause inflammatory lesions at the injection site which may persist for 14 days. In very rare cases, anaphylactic shocks have been reported in cattle.
   - Sheep: A decrease in food consumption may occur during the treatment period. The treated animals recover quickly and completely upon termination of treatment. Administration by intramuscular injection may cause inflammatory lesions at the injection site which may persist up to 28 days. Typically, these lesions are mild and transient.

   If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

   Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

   https://sideeffects.health.gov.il/

6. **Target species**

   Cattle and sheep only.

7. Method of administration and dosage

- **Cattle:** Intramuscular injection - 20 mg/kg bodyweight (1 ml/15 kg). To be administered twice, 48 hours apart, using a 16 gauge needle.
- **Sheep:** Intramuscular injection - 20 mg/kg bodyweight (1 ml/15 kg). To be injected once daily on three consecutive days.

Pharmacokinetic studies have shown that mean plasma concentrations remain above the MIC_{90} for up to 18 hours after administration of the medicine at the recommended treatment dose. Pre-clinical data provide support for the recommended treatment interval of 24 hours for target pathogens.

8. How to use the product

The dose volume given at any one injection site should not exceed 10 ml for cattle and 4 ml for sheep.
The injection should only be given in the neck.

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing. Swab septum before removing each dose. Use a sterile needle and syringe. The vial should not be broached more than 20 times; therefore the user should select the most appropriate vial size according to the target species to be treated. When treating a group of animals in one run, use of a draw-of needle that has been placed in the vial stopper is recommended to avoid excess broaching of the stopper. The draw-of suction needle should be removed after treatment.

9. Withdrawal period(s)

Meat and offal:

Cattle: 30 days

Sheep: 39 days

Milk:

Not permitted for use in lactating animals producing milk for human consumption, including pregnant animals intended to produce milk for human consumption.

10. Warnings

- Special precautions regarding the use of the medicine in treatment of target animals

  The product should be used in conjunction with susceptibility testing of the bacterium isolated from the target animal.

- Special safety precautions regarding use of the medicine in animals

  The safety of the product has not been established in sheep younger than 7 weeks of age.

- Special safety precautions to be taken by the person handling the product

  People with known hypersensitivity to propylene glycol and polyethylene glycols should avoid contact with the medicine.
  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.

- Pregnancy and lactation of the treated animal

Studies in laboratory animals have not revealed any evidence of teratogenic or foetotoxic effects. However, the effect of florfenicol on bovine and ovine reproductive performance and pregnancy has not been assessed.

Use only in accordance to the benefit/risk assessment of the treating veterinarian.

- Interaction with other medicines and other forms of interaction

  No data available.

- Overdose

  In cattle: No symptoms other than those described in section 5.

  In sheep: After administration of 3 times the recommended dose or more, a transient reduction in feed and water consumption has been observed. Additional effects included an increased incidence of lethargy, emaciation and loose feces. Head tilt was seen after administration of 5 times the recommended dose and was considered most likely as a result of irritation at the injection site in the neck.

- Incompatibility

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

11. Storage instructions

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning.
- Do not use the medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- Storage Conditions

  Store at a temperature below 25°C.

  Do not refrigerate.

  Protect from frost.

  Use the product within 28 days after opening the package.

12. Instructions 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 as toxic waste; do not discard into the wastewater.

13. Further information

- In addition to the active ingredient(s), the medicine also contains:

  N-methyl-2-pyrollidone

  Propylene glycol

  Macrogol
- What does the medicine look like and what are the contents of the package:

  Nuflor is a clear, light yellow to yellowish, somewhat viscous solution. It is packed in 50, 100 and 250 ml Type I glass vials closed with rubber stoppers with aluminum seals.
- **License holder** and address:

  Intervet Israel Ltd., Neve-Neeman Industrial Zone, Hod Hasharon 45240.
- **Manufacturer** and address:

TriRx Segre, La Grindoliere, Zone Artisanale, Segre, 49500 Segre-en-Anjou Bleu, France.

Revised in February 2021 according to MOHs guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 083-32-92230-00