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 medicine, its form and strength**

Nuflor veterinary 300 mg/mL

A solution for injection for cattle and sheep

2. **Active ingredient(s)**

Each 1 ml contains:

Active substance:
Florfenicol 300 mg

A list of excipients and allergens in the product is detailed in section 13 – "Further information".

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

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

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

Therapeutic group:

4. Antibacterial for systemic use: Amphenicols.**Contraindications:**

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

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

5. **Adverse reactions**

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Reduced food intake[1]; Loose stool[1]; Injection site inflammation[2], Injection site lesion[2]; Anaphylaxis (severe allergic reaction).

[1] Quick and complete recovery upon termination of treatment.
[2] May persist for 14 days after intramuscular and subcutaneous administration.

Sheep:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Reduced food intake[1]; Injection site inflammation[2], Injection site lesion[2].

[1] Quick and complete recovery upon termination of treatment.
[2] Mild and may persist up to 28 days after intramuscular administration.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian.

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.

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 of the medicine 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 treatment interval of 24 hours against the relevant 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 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 slaughter:

Cattle: 30 days

Sheep: 39 days

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

10. Warnings

None.

- Special precautions for safe use of the medicine in treatment of target animal

  The veterinary medicinal product should be used in conjunction with susceptibility testing of the bacterium isolated from the target animal and take into account official and local antimicrobial policies.

The safety of the veterinary medicinal 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 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.
  Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of fetotoxic effects. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.

- Pregnancy lactation and fertility of the treated animal

  The safety of the veterinary medicinal product has not been established in cattle and sheep during pregnancy, lactation or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible 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.

- 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 and not later than the expiry date of

the product.

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 product should be disposed of as toxic waste, and in accordance with local requirements; do not discard into household waste or the wastewater. Ask your veterinary how to dispose of medicines no longer required. These measures should help to protect the environment.

The veterinary medicinal product should not enter water courses as florfenicol may be dangerous for aquatic organisms.

13. Further information

- In addition to the active ingredient(s), the medicine also contains:
  N-methyl-2- pyrrolidone
  Propylene glycol
  Macrogol
- What does the medicine look like and what are the contents of the package:
  Nuflor is a clear, light yellow to straw-coloured, somewhat viscous solution. It is packed in 50, 100 and 250 ml Type I glass vials closed with rubber stopper with aluminum seal.

  Not all pack sizes may be marketed.

- **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 June 2025.

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