PATIENT PACKAGE INSERT FOR A VETERINARY PRODUCT

The medicine is only dispensed with a veterinarian's prescription

For veterinary use only

1. NAME OF THE VETERINARY MEDICINAL PRODUCT, ITS DOSAGE FORM AND CONCENTRATION

Resflor Veterinary

Solution for Injection for Cattle

2. ACTIVE INGREDIENT(S)

Each 1 ml of solution contains the active ingredients:

Florfenicol 300 mg
Flunixin meglumine 27.4 mg (equivalent to 16.5 mg of free flunixin)

3. WHAT IS THE MEDICINE INTENDED FOR

Treatment of respiratory infections in cattle caused by
Mannheimia haemolytica, *Pasteurella multocida, Mycoplasma bovis, Histophilus somni*
accompanied by fever.

THERAPEUTIC GROUP:
Florfenicol is a broad spectrum antibiotic
Flunixin meglumine is a non-steroidal anti-inflammatory agent

4. CONTRAINDICATIONS

Do not use in adult bulls intended for breeding purposes.
Do not use in animals suffering from hepatic and renal diseases.
Do not use if there is a risk of gastrointestinal bleeding.
And do not use in cases where there is evidence of altered hemostasis.
Do not use in animals known to be hypersensitive to one of the ingredients of the medicine.
Do not use in animals suffering from cardiac diseases.

5. ADVERSE REACTIONS

Subcutaneous administration of the product may result in injection site swellings that become palpable 2-3 days after injection.
This swelling may last from 15 to 36 days following the injection. This reaction may be associated with minimal to mild irritation of the subcutis. Extension into the underlying muscle has been noted in only a few instances.
After 56 days, no skin effects were observed that would require any trim-out at slaughter.

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

7. METHOD OF ADMINISTRATION AND DOSAGE

Only by subcutaneous (SC) injection in the neck.

Dose: 2 ml per 15 kg body weight administered subcutaneously. The injection should only be given in the neck region. The dose volume given at any one injection site should not exceed 10 ml.
To ensure a correct dosage of the medicine, the cow's body weight should be determined as accurately as possible.

It is recommended to start treating the animals in the early stages of the disease and to evaluate the response to treatment 48 hours after injection. Flunixin is an anti-inflammatory component which may mask a poor (minimal) bacteriological response to florfenicol in the first 24 hours after injection. If clinical signs of respiratory disease persist or increase, or if relapse occurs, treatment should be changed, using another antibiotic, and continued until clinical signs have resolved.

8. ADMINISTRATION OF THE PRODUCT

Use a dry sterile disposable syringe and needle.
Swab the septum before removing each dose.

9. WITHDRAWAL PERIOD

Slaughtering for meat: 46 days.
Milk: Do not use in lactating animals producing milk for human consumption, neither during lactation nor drying off, nor within 2 months before starting lactation.

10. WARNINGS

- Special precautions regarding use of the medicine in target animals

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, treatment should be based on local (regional or at farm level) epidemiological information about susceptibility of the bacteria.
The policy, if it exists in the State of Israel, regarding the use of antimicrobials must be considered.
Use of the product not according to the instructions given in the leaflet may increase the prevalence of bacteria resistant to florfenicol.

- Special safety precautions regarding use of the medicine in animals

Avoid use in dehydrated, hypovolemic or hypotensive animals as there is a potential risk of increased renal toxicity.
Concurrent administration of nephrotoxic drugs (which may cause renal toxicity), should be avoided.
Do not inject into calves less than 6 weeks of age.

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

Caution should be taken to avoid self-injection.

Wash hands after use.

Do not use the product in known cases of sensitivity to propylene glycol or polyethylene glycol.

- Pregnancy and lactation in the treated animal

Safety of the use of florfenicol on reproductive performance during pregnancy or lactation has not been assessed.
Use only according to the benefit/risk assessment by the responsible veterinarian.

- Interaction with other medicinal products and other forms of interaction

Concurrent use of other active substances that have a high degree of protein binding may compete with flunixin for binding and which may lead to toxic effects. Pre-treatment with other

anti-inflammatory substances may result in additional or increased adverse effects.
Accordingly a treatment-free period with such drugs should be observed for at least 24 hours before the commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.
The product must not be administered in conjunction with other non-steroidal anti-inflammatory drugs (NSAIDs) or other glucocorticosteroids.
Gastrointestinal tract ulceration may be exacerbated by corticosteroids administration in animals given NSAIDs.

- Overdose

Overdose studies undertaken on cattle for a treatment duration 3 times the recommended, showed decreased food consumption in the groups given 3 and 5 times the recommended dose. Decreased body weight was observed in the group given 5 times the recommended dose. Decreased water consumption was also observed in the group given 5 times the recommended dose.
Tissue irritation increased with increased injection volume.
Dose-related gastric ulceration was observed following treatment for 3 times the recommended duration.

- Incompatibility

This product must not be mixed with other products.

11. STORAGE INSTRUCTIONS

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach 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/bottle/carton/label. The expiry date refers to the last day of that month.
- Storage Conditions

Store below 25°C.

Do not freeze. Protect from frost.

After the first use - the content of the bottle should be used within 28 days.

12. INSTRUCTIONS FOR THE DISPOSAL OF THE PRODUCT/UNUSED PRODUCT AFTER USE

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-pyrrolidone
Propylene glycol
Citric acid
Macrogol

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

Resflor is a light yellow to straw colored solution for injection.

A glass multi-dose bottle of either 100 ml or 250 ml.

- **License holder** and address

Intervet Israel Ltd., Neve-Neeman Industrial Zone, Hod Hasharon 45240.

- **Manufacturer** and address

Vet Pharma Friesoythe, Sedelsbergerstrasse 2, 26169 Friesoythe, Germany

- **This leaflet was checked and approved by the Ministry of Health in** 05.2016.

- **Registration number of the medicine in the National Drug Registry of the Ministry of Health**
  146-43-92424-00