PATIENT PACKAGE INSERT FOR A VETERINARY PRODUCT

The medicine is only dispensed according to 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

For the list of Inactive ingredients and allergens in the preparation - see section 13 "Further information".

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 (NSAID)

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, Or in cases where there is evidence of altered hemostasis.
Do not use in animals suffering from cardiac diseases.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients detailed in section 13 "Further information".

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5. ADVERSE REACTIONS

Cattle:

Very common (>1 animal / 10 animals treated):
Injection site swelling[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports)
Anaphylactic-type reaction (severe form of allergic reaction)[2]

[1]becomes palpable 2-3 days after subcutaneous injection. The duration of the injection site swellings ranged from 15-36 days post-injection. In general, this reaction is associated with minimal to mild irritation of the subcutis. Extension into the underlying muscle was noted in only a few instances.
By 56 days post-dosing, no gross lesions were observed that would require any trim-out at slaughter.
[2]these reactions may be fatal.

Reporting side effects:
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 animal's 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 cows producing milk for human consumption, neither during lactation nor drying off, nor within 2 months before starting lactation.

10. WARNINGS

For animal treatment only.

- Special precautions for safe usein target animal

Use of the product should be based o susceptibility testing of the bacteria isolated from the animal. If this is not possible, treatment should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Official and local antimicrobial policies should be taken into account when the product is used. Use of the product not according to the instructions given in the leaflet may increase the prevalence of bacteria resistant to florfenicol.

Avoid use in dehydrated, hypovolemic or hypotensive animals as there is a potential risk of increased renal toxicity.

Concurrent administration of potential nephrotoxic drugs (renal toxicity),should be avoided.
Repeated daily dosing has been associated with abomasal erosions in the pre-ruminant calf. The product should be used with caution in this age group. The safety of the product has not been tested in calves of 3 weeks of age or less.

Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna.

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 accidental self-injection.
People with known hypersensitivity to propylene glycol and polyethylene glycol should avoid contact with the veterinary medicinal product.
Wash hands after use.

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic 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 and lactation in the treated animal

The safety of the veterinary medicinal product has not been established in cattle 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 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 thus lead to toxic effects. Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse effects and 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 in the target species for 3 times the duration of treatment, showed decreased food consumption in the groups given 3 and 5 times the recommended dose. Decreased body weights were observed in the group given 5 times the recommended dose (secondary to decreased food consumption). Decreased water consumption was observed in the group given 5 times the recommended dose.
Tissue irritation increased with increased injection volume.

Treatment at 3 times the recommended treatment duration was associated with dose-related erosive and ulcerative abomasum lesions.

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- Major incompatibilities:

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

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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 below 25°C.

Do not freeze. Protect from frost.

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

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

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from using veterinary medicinal product should be disposed of as toxic waste; do not discard into the wastewater.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

These measures should help to protect the environment.

13. FURTHER INFORMATION

- In addition to the active ingredients, the medicine also contains:

N-methyl-2-pyrrolidone
Propylene glycol
Citric acid
Macrogol

- What does the medicine look like and the content of the package:

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

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

Not all pack sizes may be marketed.

- **License holder and address**

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

- **Manufacturer and address**

Vet Pharma Friesoythe, Sedelsberger Strasse 2, 26169 Friesoythe, Germany

- Revised in August 2024 ..
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health**
  146-43-92424-00