CONSUMER PACKAGE INSERT FOR A VETERINARY PREPARATION

The medicine is only dispensed according to veterinarian's prescription
For veterinary use only

1. NAME OF THE VETERINARY MEDICINE, DOSAGE FORM AND STRENGTH

Zuprevo 180 mg/ml veterinary
Solution for S.C. Injection

2. ACTIVE INGREDIENT

Each 1 ml contains:
Active ingredient:
Tildipirosin 180 mg

A list of inactive ingredients in the product is detailed in section13 "Further Information".

3. WHAT IS THE MEDICINE INTENDED FOR:

For treatment and prevention of bovine respiratory disease (BRD) associated with *Pasteurella multocida*, *Mannheimia haemolytica* and *Histophilus somni* which are sensitive to tildipirosin.
The presence of the disease in the herd should be confirmed before preventive treatment.

Therapeutic group: antibacterials for systemic use, Macrolide.

4. CONTRAINDICATIONS:

Do not use in the cases of hypersensitivity to macrolide antibiotics or to any of the inactive ingredients.

Do not administer simultaneously with other macrolides or lincosamides (see section "Special warnings").

5. ADVERSE REACTIONS:

Cattle

Very common (>1 animal / 10 animals treated):
Immediate pain upon injection, Injection site swelling[1], Injection site pain[2], Injection site reaction[3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylaxis[4]

[1] may be present up to 21 days post treatment

[2] may be present up to 1 day post treatment

[3] pathomorphological, will largely resolve within 35 days

[4] may be fatal

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.

7. **DOSAGE FORM AND DOSAGE:**

Subcutaneous use
Inject 4 mg tildipirosin/kg body weight (equivalent to 1 ml/45 kg body weight) **once only.**

8. **METHOD OF ADMINISTRATION**

It is recommended to treat animals in the early stages of the disease and to evaluate the response to treatment two to three days later. If the clinical signs of the respiratory disease persist or increase, or if relapse occurs, treatment should be with another antibiotic until clinical signs have resolved.

For treatment of cattle 450 kg body weight and over, divide the dose so that no more than 10 ml are injected at one injection site.
The rubber stopper of the vial may be safely punctured up to 20 times. Otherwise, the use of a multiple-dose syringe is recommended.
To ensure correct dosage, body weight should be determined as accurately as possible.

9. **WITHDRAWAL PERIOD:**

Meat Slaughter: 47 days.

Do not use in lactating animals producing milk for human consumption.

Do not use in pregnant animals, which are intended to produce milk for human consumption, within 2 months of expected parturition.

10. **WARNINGS:**

There is cross resistance with other macrolides.

- Special safety precautions regarding use of the medicine in animals

Use of the product should be based on identification and susceptibility testing of the target pathogens. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

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

  People with known hypersensitivity to tildipirosin should avoid contact with the veterinary medicinal product.

  Special caution should be taken to avoid accidental self-injection, as toxicology studies in laboratory animals showed cardiovascular effects after intramuscular administration of tildipirosin. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

  Do not use in automatically powered syringes which have no additional protective system.
  Tildipirosin may cause sensitisation by skin contact. If accidental skin exposure occurs, wash the skin immediately with soap and water.
  If accidental eye exposure occurs, flush eyes immediately with clean water.
  Wash hands after use.

- Pregnancy and lactation in the treated animal

  Safety of the of the veterinary medicinal product has not been established during pregnancy and lactation. However, there was no evidence for any selective developmental or reproductive effects in any of the laboratory studies.
  Use only according to the benefit-risk assessment by the responsible veterinarian.

- Interaction with other medicinal products and other forms of interaction

  The product should not be administered with antimicrobials medicines with a similar mode of action such as other macrolides or lincosamides.

- Overdose

Overdoses of 10 times the recommended dose as well as repeated subcutaneous administration of the veterinary medicinal product only led to transient clinical signs attributed to injection site discomfort and injection site swellings associated with pain in calves.

- Special restrictions for use and special conditions for use:

Not applicable.

- 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 close 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

Shelf life after first opening - 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 waste.

13.. **FURTHER INFORMATION:**

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

  Propylene glycol
  Citric acid monohydrate
  Water for injection

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

  Clear to yellowish solution for injection.

  Type I amber glass vials with a chlorobutyl rubber stopper.

- The package contains 1 vial of 20, 50, 100 or 250 ml.
  Not all package sizes may be marketed.

- **LICENSE HOLDER NAME AND ADRESS:**

  Intervet (Israel) Ltd., Industrial Zone Neve-Ne'eman, Hod Hasharon 45240.

- **MANUFACTURER NAME AND ADDRESS:**
  Intervet International GmbH, Feldstrasse 1A, 85716 Unterschleissheim, Germany

- Revised in December 2024
- Registration number of the product in the National Drug Registry of the Ministry of Health 156-13-34415-00