The format of this leaflet was determined by the Ministry of Health and its contents checked and approved in May 2016

CONSUMER PACKAGE INSERT FOR A VETERINARY PREPARATION

The medicine is only dispensed with a veterinarian's prescription
For veterinary use only

1. Zuprevo 180 mg/ml veterinary Solution for Injection for Cattle

2. **COMPOSITION:**

Each 1 ml contains:
Active ingredient:
Tildipirosin 180 mg

A detailed list of inactive ingredients can be found in the section "Further Information".

3. **WHAT IS THE MEDICINE INTENDED FOR:**

For treatment and prevention of respiratory infections in cattle (BRD) associated with the causative: *Pasteurella multocida*, *Mannheimia haemolytica* and *Histophilus somni* which are sensitive to tildipirosin.
The presence of the infection in the herd must be confirmed before prophylactic treatment.

Therapeutic group: Macrolide antibacterials for systemic use.

4. **CONTRAINDICATIONS:**

Do not use in the case of known sensitivity to macrolide antibiotics or to any of the inactive ingredients.

5. **ADVERSE REACTIONS:**

The frequency of adverse reactions is defined as follows:

- Very common (more than 1/10 animals displaying adverse reactions during the course of one treatment)
- Common (more than 1/100 but less than 10/100 animals displaying adverse reactions during the course of one treatment)
- Uncommon (more than 1/1000 but less than 10/1000 animals displaying adverse reactions during the course of one treatment)
- Rare (more than 1/10000 but less than 10/10000 animals displaying adverse reactions during the course of one treatment)
- Very rare (less than 1/10000 animals, including isolated incidences)

Pain on injection and injection site swellings are very common in treated animals.

In isolated cases, following administration of the maximum recommended dosage of 10 ml, injection site swellings may be associated with pain on touch/palpation for about one day. The swellings are transient and will usually resolve within 7 to 16 days; in individual animals swellings may persist for 21 days. Most of the pathomorphological changes at the injection site will resolve within 35 days.

If a serious side effect occurs or other effects not mentioned in this leaflet, inform the 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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

6. **TARGET SPECIES:**
Cattle.

7. **METHOD OF ADMINISTRATION AND DOSAGE:**

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

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 over 450 kg body weight, 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 to avoid underdosing.

8. **WITHDRAWAL PERIOD:**

Meat: 47 days.

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

Do not use in pregnant animals, intended for milk production for human consumption, within 2 months of expected parturition.

9. **WARNINGS:**

- Special safety precautions regarding use of the medicine in animals

  Whenever possible, the use of a veterinary medicinal product should be based on susceptibility testing. Local regulations (assuming they exist) should be taken into account when administering antimicrobial medicines to farm animals.

- Special safety precautions to be taken by the person handling the product
  Special caution should be taken to avoid accidental self-injection, as toxicology studies in laboratory animals have shown 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 of the medicine to the attending doctor.
  Do not use in automatic syringes which have no protective system against accidental injection.

  Tildipirosin may cause sensitization by skin contact. If accidental skin exposure occurs, wash the exposed area 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 use of this medicine during pregnancy or lactation has not been tested during pregnancy or lactation. However, there has been no evidence for any developmental or reproductive effects in any of the laboratory studies.
  Use only according to the benefit-risk assessment by the attending veterinarian.

- Interaction with other medicinal products and other forms of interaction

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

- Overdose

  In calves, following a single subcutaneous injection at a dose 10 times the recommended dose (40 mg/kg body weight), and repeated subcutaneous injections of tildipirosin (on three occasions at 7 day intervals) at doses of 4, 12 and 20 mg/kg body weight, other than transient clinical signs attributed to injection site discomfort and injection site swellings associated in a few animals with pain, tolerance to the injected doses was observed.

- Incompatibility

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

10. **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.
- 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.

11. **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.

12. **FURTHER INFORMATION:**

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

  Propylene glycol
  Citric acid monohydrate
  Water for injection

- What does the medicine look like and what are the contents 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 and address:**

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

- **Manufacturer and address:**
  Intervet International GmbH, Feldstrasse 1a, 85716 Unterschleissheim, Germany

- **This leaflet was checked and approved by the Ministry of Health in**
  May 2016.
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health**
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