Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

Veterinary medicine package leaflet

This medicine is dispensed with a veterinarian's prescription only

For use in animals only

1) Name, form and strength of the veterinary medicine:

ZACTRAN Veterinary

Solution for subcutaneous or intramuscular injection

For veterinary use in cattle, pigs and sheep only

2) The active ingredient and its quantity per dosage unit:

The active ingredient and its concentration in the solution: Gamithromycin 150 mg/ml

For the list of all inactive ingredients and allergens in the medicine - see section 13.

Read the entire leaflet carefully before you start using this medicine.

This leaflet contains concise information about the medicine. If you have any further questions, consult the veterinarian or pharmacist.

3) What is the medicine intended for?

The medicine is intended for cattle, for treatment and metaphylaxis of pneumonia (bovine respiratory disease; BRD) associated with *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni*.

In metaphylaxis: the presence of the disease in the herd should be established before using the medicine.

The medicine is intended for pigs, for treatment of pneumonia (swine respiratory disease; SRD), associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida,* and *Haemophilus parasuis*.

The medicine is intended for sheep, for the treatment of infectious pododermatitis (foot rot) associated with virulent *Dichelobacter nodosus* and *Fusobacterium necrophorum* requiring systemic treatment.

Therapeutic group: The drug belongs to the group of macrolide antibiotics.

4) Contraindications:

Do not use the medication:

- If the cattle, pig and/or sheep are sensitive (allergic) to the active ingredient, macrolide antibiotics, or to any of the excipients that the medicine contains.
  The active ingredient is specified in section 2 and the excipients are detailed in section 13.
- Do not use simultaneously with other macrolides or lincosamides.
- Information regarding withdrawal periods before slaughtering, use of dairy animals (produce milk for human consumption) and use during pregnancy - see section 9 "**Withdrawal period**".

5) Side effects:

Like with all medicines, using this medicine may cause side effects in some cattle, pigs and/or sheep. Do not be alarmed by this list of side effects. The cattle, pigs and/or sheep may not experience any of them.

During clinical trials with the medicine transient injection site swelling was observed.

Very common side effects (displayed by more than 1 in 10 treated animals): In cattle, visible injection site swelling associated with occasional slight pain may develop for one day. The swelling typically resolves within 3 to 14 days but may persist in some animals for up to 35 days after treatment.

Common side effects (displayed by 1-10 in 100 treated animals): In pigs and sheep, mild to moderate injection site swelling may develop. In sheep it is accompanied with occasional pain evident for one day. These reactions are transient and typically resolve within 2 (pigs) to 4 (sheep) days.

If one of the side effects worsens, or when the cattle, pig and/or sheep suffer from a side effect not mentioned in the leaflet, you should consult the veterinarian.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il/

6) Target animals:

The medicine is intended for use in cattle, pigs and sheep only.

7) Dosage and method of administration:

Always use according to the veterinarian's instructions. You should check with the veterinarian or the pharmacist if you are not sure about the dose or about how to administer this medicine. Only the veterinarian will determine the dose and how to treat with this medicine. **Do not exceed the recommended dose.**

Administration:

Cattle and sheep: subcutaneous (S.C) administration only.

Pigs: intramuscular (I.M) administration only.

Dosage: A single dose of 6 mg gamithromycin/kg body weight (equivalent to 1 ml/25 kg body weight). To ensure the correct dose, body weight should be determined as accurately as possible.

Injection site in cattle and pigs: injected in the neck area.

Injection site in cattle sheep: injected in the anterior to the shoulder.

Vial information: The cap may be safely punctured up to 50 times with a 16G needle and up to 80 times with an 18G needle. For multiple vial entry, an automatic dosing device is recommended to avoid excessive broaching of the stopper.

8) How to use this medicine:

- Cattle: for treatment of cattle over 250 kg, divide the dose so that no more than 10 ml are injected at a single site.
- Sheep: for treatment of sheep over 125 kg, divide the dose so that no more than 5 ml are injected at a single site.
- Pigs: divide the dose so that no more than 5 ml are injected at a single site.

9) Withdrawal period:

Withdrawal periods before slaughter:

Cattle: 64 days.

Sheep: 29 days.

Pigs: 16 days.

In dairy cows and sheep (produce milk for human consumption): do not use the medicine.

In pregnant cows and sheep which are intended to produce milk for human consumption: Pregnant sheep - do not use 1 month of expected parturition. Pregnant cows - do not use two months of expected parturition.

10) Warnings:

- **Special warnings about treating the target animal with this medicine:** Cattle and pigs: None. Sheep: The efficacy of antimicrobial treatment of pododermatitis (foot rot) might be reduced by other factors, such as wet environmental conditions, as well as inappropriate farm management. Treatment of foot rot should therefore be undertaken along with other flock management tools, for example providing dry environment. Antibiotic treatment of benign foot rot is not considered appropriate.
- **Special safety precautions for use in animals:** Unknown.
- **Special safety precautions for the person administering the medicine:** People who are sensitive (allergic) to the active ingredient, macrolide antibiotics, or to any of the excipients that the medicine contains, should avoid contact with the medicine. The active ingredient is specified in section 2 and the excipients are detailed in section 13.
- Gamithromycin may cause irritation to the eyes and skin. Avoid contact with eyes or skin. If eye or skin exposure occurs, wash immediately with clean water. In case of accidental self-injection, seek medical advice. Bring the package of the preparation and show it to the treating medical staff.
- Wash hands after use.
  If a person accidentally swallows the medicine, especially if it is a child, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.
- **Gestating and lactating animal patients:** The safety of the medicine during pregnancy and lactation has not been established in cattle, sheep and pigs. In these cases, use only according to the risk/benefit assessment by the responsible veterinarian.
- **Drug interactions and other interactions:** Cross resistance may occur with other macrolides. Avoid simultaneous administration of antimicrobials with a similar mode of action such as other macrolides or lincosamides.
- **Overdose:** Field trials demonstrated that gamithromycin has a wide safety range when administered to cattle, pigs and sheep. When administered to animals in overdose of 1, 3, and 5 times the recommended dose, and repeated 3 times at 1, 5 and 10 days, injection site reactions were noted in a dose related manner.
- **Incompatibility:** Do not mix the medicine with other medicines or medicinal products.

11) Storage instructions:

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store at a temperature below 30°C.
- **Shelf life after first opening the primary packaging:** 28 days, but no later than the expiry date of the medicine.

12) Instructions for the disposal of drug/waste materials after use:

- Dispose of any remaining veterinary medicine or waste obtained from using a veterinary medicine in the same manner as toxic waste; do not discard into a sewer.
- Ask your pharmacist or veterinarian how to dispose of expired or no longer required medications. These measures should help to protect the environment.

13) Additional information:

- **In addition to the active ingredient, this medicine also contains the following excipients:** Monothioglycerol, Succinic Acid, Glycerol Formal.
- **What the medicine looks like and contents of the pack:** The medicine looks like a clear colorless or pale yellow solution.
- The solution is packed in glass or polypropylene vials, closed with a rubber stopper. The vial is packed in a cardboard box.
- **Pack size:** Glass vials with a rubber stopper containing 50, 100 and 250 ml of solution. Plastics vials with a rubber stopper containing 100 and 250 ml of solution.
- The volume of the solution in the vial appears on the cardboard packaging.

- Not all pack sizes may be marketed.
- **Registration holder:** Beit Erez Havat Milatin Ltd., P.O.B. 209, Mishmar Hashiva 5029700.
- **Manufacturer:** Boehringer Ingelheim Vetmedica GmbH, Ingelheim am Rhein, Germany (by Boehringer Ingelheim Animal Health France, Toulouse, France).

The medicine is intended for cattle, pigs and sheep.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 153-34-33711-00

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