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:

Equest Pramox Veterinary Oral Gel (per os)

2. ACTIVE INGREDIENT

Moxidectin 1.95 %w/w

Praziquantel 12.17 %w/w

List of the inactive ingredients in section 13.

3. WHAT IS THIS MEDICINE INTENDED FOR?

For treatment of mixed cestodes and nematodes or arthropods infections in horses, caused by:

moxidectin and praziquantel sensitive strains of large strongyles, small strongyles (adults and intraluminal larval stages), ascarids and other species, and tapeworm (adults).

The egg reappearance period of small strongyles is 90 days.

The product is effective against developing intramucosal L4 stages of small strongyles.

At 8 weeks after treatment, early (hypobiotic) EL3 stages of small strongyles are eliminated.

4. CONTRAINDICATIONS

Do not administer to young foals less than 6.5 months old.

Do not use in case of known hypersensitivity to the active ingredients or to any of the inactive ingredients in the medicine.

The medicine is intended for horses only. Dogs and cats that come into contact with the gel or with a used syringe may suffer from side effects due to the dosage of moxidectin.

5. SIDE EFFECTS

Mouth pain, flaccid lower lip, swelling of the muzzle, hypersalivation and anorexia have been observed in rare cases. Lack of muscle control (ataxia) has been reported on rare occasions and lethargy in very rare cases. These effects are transient and disappear spontaneously. In case of very high worm burdens, destruction of the parasites may cause a mild stomachache (colic) and diarrhoea in the treated animal. You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry 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

Horses

7. METHOD OF ADMINISTRATION AND DOSAGE

A single oral dose of 400 µg moxidectin/kg bodyweight and 2.5 mg praziquantel/kg bodyweight using the calibrated syringe of one gradation per 25 kg bodyweight. To ensure administration of the correct dosage, bodyweight should be determined as accurately as possible; accuracy of the dosing should be checked.

Use of a scale or weight tape is recommended to ensure accurate dosing. Before administering the first dose, hold the syringe with the capped end pointing to the left so that you can see the weight measurements and tick marks (small black lines). Set the syringe to zero by moving the dial ring so the left side is set at the first full black mark and then depress the plunger, safely discarding any leftover substance that is expelled. To determine the dosage of the medicine, hold the syringe as previously described. Each tick mark relates to 25 kg of bodyweight and to 10 mg moxidectin/62.5 mg praziquantel. Turn the dial ring until the left side of the ring lines up with the weight of the animal.

A single syringe treats a 700 kg horse.

For cestode treatment, the dose of praziquantel in the medicine is at the top end of the dosing range.

Veterinary advice should be given on appropriate dosing programmes and stock management to achieve optimum parasite control.

8. HOW TO USE THIS MEDICINE

For optimum control of bots, the medicine should be administered in the autumn, after the end of the fly season and before spring as the larvae may start to pupate and therefore are less sensitive to treatment.

9. WITHDRAWAL PERIOD

Not applicable.

10. WARNINGS

- Special warnings about treating the target animal with this medicine

  Avoid the following practices, which may increase the risk of development of resistance and negatively impact the efficacy of the therapy:
  - Too frequent and repeated use of anthelmintics - medications for the treatment of intestinal worms from the same class, over an extended period of time.
  - Under-dosing due to underestimation of bodyweight, misadministration or incorrect calibration of the injection device (If any).

  Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. faecal egg count reduction). If the results of the tests indicate resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

  Parasite resistance to a particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

  The veterinarian should give advice regarding appropriate dosing programmes and stock management to achieve adequate parasite control for both tapeworm and roundworms.
- Special warnings about the safety of using this medicine in animals

  To avoid overdosing, ensure that the dose administered matches the weight of the foals, especially low body weight foals or pony foals.

  Do not use the same syringe to treat several horses, except when the horses are part of the same herd or in direct contact with each other.
- Special safety precautions for the person administering the medicine

  This medicine may cause eye irritation, skin irritation and skin sensitisation. Avoid direct contact with eyes and skin.

  Use of protective gloves is recommended.

  Wash hands or any area exposed to the medicine after use.

  Do not smoke, drink or eat while administering or using the medicine.

  In the event of eye contact with the medicine, flush the eye with copious amount of clean water and seek medical care.

  In case of accidental ingestion, seek medical care and show the doctor the package insert.
- Pregnancy and lactation in the treated animal

  The medicine has been shown to be safe for use in breeding, pregnant and lactating mares.

  The administration of the medicine does not affect the fertility of the mares.
- Interactions with other medicines and other forms of interaction

  The effects of GABA agonists are increased by moxidectin.
- Overdose

  Transient side effects may occur at the recommended treatment dose in foals. In adult horses transient side effects may occur at 3 times the recommended dose. The symptoms are: depression, inappetence, flaccid lower lip and/or lack of muscle control (ataxia) in the 8 to 24 hours following treatment. Symptomatic treatment is not generally necessary, and recovery is generally complete within 24 to 72 hours. There is no specific antidote.
- Incompatibility

  None known.

  Special precautions regarding the environmental impact of the medicine:

  Moxidectin is a very persistent, bioaccumulative and toxic (PBT) substance; therefore, exposure of the environment to moxidectin must be limited to the extent possible. Treatments should be administered only when necessary and should be based on faecal egg counts or evaluation of the risk of infestation at the animal and/or herd level. In order to reduce the emission of moxidectin to water and based on the excretion profile of moxidectin when administered as the oral formulation to horses, treated animals should not have access to watercourses during the first week after treatment.

  Like other macrocyclic lactones, moxidectin has the potential to adversely affect non-target organisms:
  - Faeces excreted by treated animals may temporarily reduce the abundance of dung feeding organisms. Following treatment of horses, levels of moxidectin that are potentially toxic to dung beetles and flies may be excreted over a period of more than 1 week and may decrease dung fauna abundance.
  - Moxidectin is toxic to aquatic organisms, including fish. The medicine should be used only according to the label instructions.

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 below 25°C.
- Shelf-life after opening: Use within six months of first opening.

12. INSTRUCTIONS FOR THE DISPOSAL OF THE UNUSED PRODUCT OR WASTE MATERIALS

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. The medicine is toxic for fish and aquatic organisms. After use, wrap the syringe with its content in a bag or sealed container and send them for destruction at an appropriate waste site. Do not contaminate pools, rivers, lakes, sewage systems, etc. with the syringe or its content.

13. ADDITIONAL INFORMATION

- **In addition to the active ingredient, this medicine also contains:**
  Benzyl alcohol
  Silica, colloidal anhydrous
  Ethanol, anhydrous
  Butylhydroxytoluene (BHT)
  Polysorbate 80
  Ethyl cellulose
  Propylene glycol dicaprylocaprate (Miglyol 840)
- **What the medicine looks like and contents of the pack:**
  14.4 gram syringe
- **Pack sizes:**
  Cardboard box with a single syringe.
- **Registration holder:**
  Zoetis Israel Holding B.V., 5 Atir Yeda Street, Kfar Saba.
- **Manufacturer's name:**
  Zoetis Manufacturing & Research Spain, S.L.
  CTRA. Camprodon, "La Riba", Vall De Bianya, Girona, Spain
- **Registration number of the medicine in the Ministry of Health National Drug Registry:**
  146 03 92434 00

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