

BIOMEC 10 mg/ml injection solution

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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Komenského 212,
683 23 Ivanovice na Hané
Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT BIOMEC 10 mg/ml injection solution Ivermectinum

3. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:

Ivermectinum 10.0 mg in 1 ml.

Excipients:

Glycerol formal, Propylene glycol

4. INDICATION(S)

This product is indicated for efficient treatment and prevention of the spread of diseases caused by the following parasites:

Cattle:

Gastrointestinal roundworms (adults and developmental stages):

Ostertagia ostertagi (adults, L₄ and L₅ including inhibited larvae)

Ostertagia lyrata (adults)

Haemonchus placei (adults, L₄ and L₅)

Trichostrongylus axei (adults and L₄)

Cooperia oncophora (adults and L₄)

Cooperia punctata (adults and L₄)

Cooperia pectinata (adults and L₄)

Oesophagostomum radiatum

(adults, L₄ and L₅)

Bunostomum phlebotomum

(adults, L₄ and L₅)

Nematodirus helveticus (adults)

Nematodirus spathiger (adults)

Strongyloides papillosus (adults)

Toxocara vitulorum (adults)

Trichuris spp. (adults)

Lungworms:

Dictyocaulus viviparus (adults, L₄ including inhibited larvae)

Eye worms:

Thelazia spp. (adults)

Warble flies (all parasiting stages):

Hypoderma bovis

Hypoderma lineatum

Sarcoptes:

Psoroptes bovis

Sarcoptes scabiei var. *bovis*

Lice:

Linognathus vituli

Haematopinus eurysternus

Solenopotes capillatus

The product can be used adjuvantly to prevent the spread of *Chorioptes bovis*, complete elimination, however, may not result.

Persistence of the effect in cattle:

The effect of the product preventing the spread of *Haemonchus placei* and *Cooperia* spp. will last 2 weeks, provided that the recommended dose of 1 ml per 50 kg live weight was administered.

For *Ostertagia ostertagi* and *Oesophagostomum radiatum* the efficiency period is 21 days, and for *Dictyocaulus viviparus*, 28 days after treatment.

Sheep:

Gastrointestinal roundworms:

Haemonchus contortus (adults, L₄ and L₅)

Ostertagia circumcincta (adults, L₄ and L₅)

Trichostrongylus axei (adults)

Trichostrongylus colubriformis

(adults, L₄ and L₅)

Trichostrongylus vitrinus (adults)

Nematodirus filicollis (adults and L₄)

Nematodirus spathiger (L₄ and L₅)

Cooperia curticei (adults, L₄)

Oesophagostomum columbianum

(adults, L₄ and L₅)

Oesophagostomum venulosum (adults)

Chabertia ovina (adults, L₄ and L₅)

Trichuris spp. (adults)

Strongyloides papillosus (L₄ and L₅)

Gaigeria pachyscelis (adults, L₄ and L₅)

Lungworms:

Dictyocaulus filaria (adults, L₄ and L₅)

Protostrongylus rufescens (adults)

Nasal bot flies (all parasiting stages):

Oestrus ovis

Mange:

Psoroptes communis var. *ovis* (1)

Sarcoptes scabiei

Psorergates ovis

(1) When treating sheep against *Psoroptes communis*, administer two injections within 7 days. A single administration may only reduce the number of the parasites, making the impression that mange was eradicated.

Pigs:

Gastrointestinal roundworms:

Ascaris suum (adults and L₄)

Hyostrogylus rubidus (adults and L₄)

Oesophagostomum spp. (adults and L₄)

Strongyloides ransomi (adults and somatic larvae)*

Lungworms:

Metastrongylus spp. (adults)

Other worms:

Stephanurus dentatus (adults and L₄)

Lice:

Haematopinus suis

The product does not act against lice eggs, whose development takes 21 days. Thus their elimination may require repeated treatment.

Mange:

Sarcoptes scabiei var. *suis*

* Administered to pregnant sows 7–14 days before parturition, the product will efficiently prevent the transfer of *S. ransomi* from the sows to the piglet in milk.

5. CONTRAINDICATIONS

Do not administer intravenously or intramuscularly.

If the animals produce milk for human consumption, do not administer the product during lactation or 28 days before expected parturition.

6. ADVERSE REACTIONS

Following subcutaneous administration, some animals may exhibit temporary restlessness and occasional occurrence of soft tissue oedema at the site of injection. Such reactions will subside spontaneously.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, sheep, pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Subcutaneous administration.

Cattle:

Recommended dose is 0.2 mg ivermectin per kg live weight (corresponding to 1 ml of the product per 50 kg live weight).

Administer the product subcutaneously into loose skin in front of or behind the shoulder blade.

If the animals suffer from hypodermosis, treat the cattle as soon as possible after the warble attack.

Treatment of cattle affected by hypodermosis:

Ivermectin is efficient against all stages of subcutaneous warbles in cattle, the time of treatment, however, is a critical factor.

Cattle should be treated immediately when the warble attack is over. In fact, action against the larvae while they are present in the animal's vital organs may induce adverse reactions in the host. Action against *Hypoderma lineatum* when this parasite is present in the tissues of the oesophagus may result in tympanites. Action against *Hypoderma bovis* when this parasite is present in the vertebral channel may result in dizziness or paralysis. Thus, cattle should be treated before or after the finish of those developmental forms.

Sheep:

Recommended dose is 0.2 mg ivermectin per kg live weight (corresponding to 0.5 ml of the product per 25 kg live weight).

Administer the product subcutaneously into the loose skin between the shoulders. When administering the product to sheep before shearing, make sure that the needle penetrated the wool and skin before injecting the dose.

If treating the animals against psoroptic mange, repeat the treatment in 7 days.

Pigs:

Recommended dose is 0.3 mg ivermectin per kg live weight (corresponding to 1 ml of the product per 33 kg live weight). The product must be administered subcutaneously, in the neck area, at the recommended dose.

9. ADVICE ON CORRECT ADMINISTRATION

The injection solution may be administered by using any normal syringe pump or syringe.

In order to adhere closely to the recommended dose, determine the animal's live weight as accurately as possible.

10. WITHDRAWAL PERIOD

Sheep, pigs: meat: 28 days

Cattle: meat: 49 days

Milk: Animals producing milk for human consumption should not be treated with the product during lactation or 28 days before expected parturition.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach of children.

Store below 25 °C.

Protect from light.

Shelf life after first opening the container:

28 days.

Do not use after the shelf life stated on the box.

12. SPECIAL WARNING(S)

Keep out of the reach of children.

Do not store together with food or animal feed.

Special warnings for each target species

Due to the risk of development of resistance, which may result in inefficient therapy, be careful in the use of this product. Do not:

- administer anthelmintics from the same group too often, repeatedly, or too long, or
- underdose the product due to inaccurate determination of the animal's live weight or to the use of an inappropriate administration routine.

Examine suspect clinical cases for resistance to anthelmintics by using appropriate tests (such as FECRT, the faecal egg count reduction test). Where resistance to a certain anthelmintic is

confirmed by the tests, use an anthelmintic from a different group and having a different way of action.

The use of this product must be based on local epidemiological information regarding the sensitivity of nematodes and recommendations as to how to prevent further development of resistance to anthelmintics.

Special precautions for use in animals
Do not administer to wet or dirty animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Do not smoke, drink or eat while handling the product. Wash your hands thoroughly with soap and water after handling the product.

The product may cause skin and eye irritation. Avoid contact of the product with skin and eyes. In case of contact with eyes or skin, wash the exposed site immediately with plenty of water. If symptoms have developed, seek medical advice.

Avoid accidental self injection. In case of accidental self-injection, seek medical attention immediately and show this package leaflet or label to the general practitioner.

Individuals with known hypersensitivity to ivermectin or to any of the excipients should avoid contact with this veterinary medicinal product.

The product should not be administered by pregnant or breastfeeding women, elderly people, patients with CNS disorders, epileptics, patients with severe hepatic insufficiency, or patients with cardiovascular problems.

Pregnant and breastfeeding women should exercise care when administering the product.

Protective personal aids including protective gloves should be used when handling the veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

The product is toxic to aquatic organisms. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be

disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED November 2012

15. OTHER INFORMATION

For animal treatment only.

To be supplied only on veterinary prescription.

For additional detailed information regarding this veterinary medical product, please contact your local representative of the marketing authorisation holder.

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