INJECTION

Actimec

3.15%

For Veterinary Use Only

Statement of active substance (s) and other ingredients:
Each ml contains
Ivermectin 3.15%

Indications:
CATTLE: The product is indicated for the treatment and control of the following species of gastro-intestinal roundworms, lungworms, eyeworms, warbles, mites and lice.
Gastrointestinal roundworms (adult and fourth-stage larvae):
Ostertagia spp. (including inhibited *O. ostertagi*)
Haemonchus placei
Trichostrongylus axei
T. colubriformis
Cooperia spp.
Oesophagostomum radiatum
Strongyloides papillosus (adult)
Nematodirus helvetianus (adult)
N. spathiger (adult)
Bunostomum phlebotomum
Toxocara vitulorum
Trichuris spp (adult)
Lungworms (adult and fourth-stage larvae):
Dictyocaulus viviparous
Eye worms (adult):
Thelazia spp.
Warbles:
Hypoderma bovis
H. lineatum
Mange mites:
Psoroptes bovis
Sarcoptes scabiei var. bovis
Sucking lice:
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus
This product may also be used as an aid in the control of biting lice (*Damalinia bovis*) and the mange mite (*Chorioptes bovis*), but complete elimination may not occur.
Sheep
The product is indicated for the treatment and control of the following species of gastro-intestinal roundworms, lungworms, nasal bots and mites.
Gastrointestinal roundworms (adult and fourth-stage larvae):
Ostertagia circumcincta including inhibited larvae
O. trifurcata
Haemonchus contortus including inhibited larvae
Trichostrongylus axei (adults)
T. colubriformis and T. vitrinus (adults)
Cooperia curticei
Oesophagostomum columbianum
O. venulosum (adults)
Nematodirus filicollis
Chabertia ovina
Trichuris ovis (adults).
Benzimidazole-resistant strains of *Haemonchus contortus* and *Ostertagia circumcincta* are also controlled.
Lungworms:
Dictyocaulus filaria (adult and fourth-stage larvae)
Protostrongylus rufescens (adults)
Nasal Bots (all larval stages)
Oestrus ovis
Mange mites:
*Psoroptes ovis** (adult and immature stage)
For the treatment and control of sheep scab *Psoroptes ovis*, two injections with a seven-day interval are required to treat clinical signs of scab and to eliminate mites. Benzimidazole-resistant strains of *Haemonchus contortus* and *Ostertagia circumcincta* are also controlled.

Contraindications:
Do not use by the intravenous or intramuscular route.
Adverse reactions including fatalities in dogs may occur.
In sheep, treatment of psoroptic mange (sheep scab) with one injection is not recommended because, although a clinical improvement may be seen, elimination of all mites may not occur.

Adverse reactions:
Studies have shown a wide safety margin and, at the recommended dosage, no adverse effect on breeding performance were observed.
At therapeutic doses, ivermectin has no adverse effect on cattle or sheep since it does not readily penetrate their central nervous systems.
Transitory discomfort has occasionally been observed in some cattle and sheep following subcutaneous administration.
A low incidence of soft-tissue swelling at the injection site has been observed in those species. These reactions have disappeared without treatment.

Target species:
Cattle, buffalo, camel, sheep and goat.

Dosage for each species, route(s) and method of administration:
The injection may be given with any standard automatic or single-dose or hypodermic syringe. Use of 17-gauge ½-inch needle is suggested. Replace with a fresh sterile needle after every 10 to 12 animals. Injection of wet or dirty animals is not recommended. If using a single-dose or hypodermic syringe, use a separate sterile needle to withdraw the product from the pack.
To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (if any).Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g Faecal Egg Count Reduction Test).
Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used. Resistance to ivermectin (an avermectin) has been reported in Teladorsagia in sheep and goats within the EU. Resistance is common in Haemonchus in sheep outside the EU. It has been reported in Cooperia oncophora in cattle within the EU, in Teladorsagia in cattle in developed countries such as New Zealand and Haemonchus in cattle outside the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

Dosage
The product should be given only by subcutaneous injection.
Cattle/buffalo/camel/sheep/goat: 1 ml per 150 kg of bodyweight under the loose skin in front of or behind the shoulder.

Withdrawal period (s):
Meat: 35 days.
Product is not recommended for use in animals producing milk for human consumption.

Special storage precautions:
Keep out of the reach of children.
Following withdrawal of the first dose, use the product within 6 months.
Discard unused material
Avoid introduction of contamination.
Protect from light.
Store between 15-25°C in a cool and dry place.
Keep vial in outer carton
When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

OPERATOR WARNINGS
Do not smoke, eat or drink whilst handling the product. Wash hands after use.
Take care to avoid self-administration: the product may cause irritation and/or pain at the site of injection.

SPECIAL PRECAUTIONS FOR USE
As this product does not contain any antimicrobial preservative, swab septum before removing each dose. Use sterile needle and syringe.

SPECIAL WARNINGS
Sheep scab (Psoroptes ovis) is an extremely-contagious external parasite of sheep. Following treatment of infected sheep, great care must be taken to avoid reinfestation, as mites may be viable for up to 15 days off the sheep. It is important to ensure all sheep which have been in contact with infected sheep are treated. Contact between treated, infected and non-treated, non-infected flocks must be avoided until at least 7 days after the last treatment.
Adequate vaccination of sheep against clostridial infections is strongly recommended.

USE DURING PREGNANCY, LACTATION OR LAY:
Product is not recommended for use in animals producing milk for human consumption.

OVERDOSAGE
Cattle: single doses of 4 mg of ivermectin per kg (20 times the use level) given subcutaneously resulted in ataxia and depression.
For those species, no antidote has been identified. However, symptomatic therapy may be beneficial.

Special precautions for the disposal of unused product or waste materials if any:
Dispose of any unused product and empty containers in accordance with guidance from your local waste-regulation authority.
EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate ponds, waterways or ditches with the product or used container.

Other information:
Keep vial in outer carton.
BP Vet Specs.

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Manufactured by:
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ISO CERTIFIED COMPANY