

For Veterinary Use Only.

Ultramec[®] Forte

2% Solution for Injection

Veterinary Endectocide

COMPOSITION:

Ultramec Forte 2% Solution for Injection is a clear, light yellow colored, odourless solution containing 20 mg of ivermectin per ml.

PHARMACOLOGICAL PROPERTIES:

Active substance in Ultramec Forte 2% Solution for Injection, ivermectin, is an avermectin derivative, and is fermentation product of *Streptomyces avermitilis*. It is a synthetic chemotherapeutic. Ivermectin is formed 80% by 22-23 dihydro-ivermectin B_{1a} at least, and 20% by 22-23 dihydro-ivermectin B_{1b} components at most. Ivermectin prevents motor nerve impulse passing by keeping chlorine (Cl⁻) channels open by increasing Gama Amino Butyric Acid (GABA) release in motor ganglion synopsis (nematodes) or neuromuscular endplates (arthropods) in parasites; parasite gets paralyzed and dies. However ivermectin could not pass blood/brain barrier, and could not influence GABA placed in central nerve system, possibly because it is a large macrolide, it does not form any negative effect considering mammals. When administering orally maximal plasma concentration reach time is 1.3 day, and plasma elimination half life in sheep is 3.5 days, and 8 days in cattle, in average. It moves as bonded to plasma proteins Distribution volume is high. It influences all tissues and body fluids excluding cranial-cerebrospinal fluid. Because it is released and eliminated slowly following its storage in fat tissues its permanent effects range between 2-4 weeks depending on types of parasite. It is excreted essentially through bile discharge and minimally through urination. More than 90% of the substance excreted is non-metabolized main compound.

AREA OF USE / INDICATIONS:

Ultramec Forte 2% Solution for Injection is used in order to treat and control internal and external parasites specified below in cattle and sheep.

In Cattle:

Gastrointestinal Nematodes	: <i>Heamonchus placei</i> , <i>Ostertagia sp.</i> , <i>O. ostertagi</i> (adults, larval stages, hypobiotic larvae), <i>O. lyrata</i> (adults ,L ₄ larvae), <i>Mecistocirrus digitatus</i> (adult), <i>Trichostrongylus axei</i> , <i>T. colubriformis</i> , <i>Cooperia oncophora</i> , <i>C. punctata</i> , <i>C. pectinate</i> , <i>Cooperia sp.</i> <i>Nematodirus helvetianus</i> (adults), <i>N. spathiger</i> (adults), <i>Oesophagostomun radiatum</i> , <i>Strongylus papillosus</i> (adults), <i>Bunostomum phlebotomum</i> , <i>Toxacara vitulorum</i>
Pulmonary Enterobius Vermicularis	: <i>Dictyocaulus viviparus</i>
Skin Filariasis Factors	: <i>Paralilarla bovicola</i>
Gizzard Nematodes	: <i>Thelezia sp.</i> (adult)
Warbel Fly Larvae	: <i>Hypoderma bovis</i> (larva), <i>Hypoderma lineatum</i> (larva), <i>Dermatobia hominis</i> (larva)
Screwworms (during parasitic stage)	: <i>Chrysomya bezziana</i> , <i>Cochlionya hominivorax</i>
Mange Factors	: <i>Psoroptes communis bovis</i> , <i>Psoroptes communis ovis</i> , <i>Sarcoptes scabei bovis</i> , <i>Chorioptes bovis</i>

Lice : *Linognathus vituli*, *Haematopbinus eurystemus*, *Solenopotes capillatus*, *Damalima bovis*

Ticks (some single host ticks, soft ticks) : *Boopnylus sp.*, *Ornithodurus savignyi*

In sheep:

Gastro-intestinal Nematodes : *Heamonchus sp.*, *Ostertagia sp.*, *Trichostrongylus sp.*, *Cooperia sp.*, *Nematodirus sp.*, *Oesophagostomun sp.*, *Strongylus papillosus*, *Cbaberthia ovina*, *Tricburis ovis*

Pulmonary Enterobius Vermicularis : *Dictyocaulus Ularla*

Mange Factors: : *Sarcoptes scabei var. ovis*, *Psoroptes ovis*, *Cborioptes bovis var. ovis*

Lice : *Bovicola ovis*, *Linognathus pedalis*, *L ovillus*, *L stenopsis*

Sheep Wool Fly : *Melophaga ovlnus*

Nose Worms: : *Oestrus ovis*

Screwworms: : *Chrysomia bezziani*

Ticks (Single host) : *Boopnylus sp.*, *Ornithodurus lahorensis*

USAGE AND DOSAGE:

Ultramec Forte 2% Solution for Injection is injected by intramuscularly and subcutaneous Unless recommended otherwise by veterinary surgeon Ultramec Forte 2% Solution for Injection is administered by being calculated at 200 ug/kg dose IM or SC in cattle and sheep. The practice dose of Ultramec Forte 2% Solution for Injection is 1 ml/100 kg live weight.

SHEEP		CATTLE	
Live weight (kg)	Dose (ml)	Live weight (kg)	Dose (ml)
20-25	0,25	50-100	0,5-1
25-50	0,5	100-200	1-2
50-75	0,5-0,75	200-400	2-4

SPECIFIC CLINICAL PARTICULARS AND SPECIAL WARNINGS FOR TARGET SPECIES:

- It has been observed paresis and paraplegia to be formed as a result of dying *Hypoderma bovis* larvae entering into medulla spinalis during migration, and salivation depending on esophageal stroke, and secondary timpani to be formed as a result of dying *Hypoderma lineatum* larvae. For struggle against warble it preferable the administration to be executed flowing Warble Fly season end.
- Administrating Ultramec Forte 2% Solution for Injection may prevent screwworm infections for 14 days in breeding applications including castration, franking, and putting ear tag numbers because infestation control efficiency against screwworm, *Chrysomia bezziana* larvae is maintained for 2 weeks following the administration.
- It has been determined ivermectin duration of permanent effects against infective enterobius vermicularis larvae to be changed between 2-4 weeks as per type of nematodes
- Regardless which parasite is the issue it is a must to cover all animals in herd in order to be successful in the struggle against parasites.
- Parasitic development stages, contagion density, climate and grazing land conditions, grazing land programs, and other environmental factors for targeted parasites should be taken into account when determining administration time and administration frequency. Consult a veterinary surgeon for the most convenient and efficient parasite control program in that area.

- In cattle taken into barnyard feeding one time Ultramec Forte 2% Solution for Injection administration during admission is sufficient generally.
- The administration is to be executed for a few times in a year in animals cropping on grazing land continuously or at intervals. Consult a veterinary surgeon in order to determine the most convenient disinfection times, number of disinfection, and administration intervals according to the regional conditions and target parasite situation.
- In young animals first time on grazing land the best results may be acquired in grazing season of that year when 3 administrations, at 3rd, 8th, and 13th weeks following the first time in grazing land, are carried out.
- Psoroptic mange treatment in sheep is recommended to be executed at 7 day intervals and for a total of 2 times for the best results.

Use during pregnancy: Safe in pregnant women at the recommended doses.

UNDESIRE/SIDE EFFECTS

Temporary pain and puffiness may occur on administration area. Ivermectin administered in case hypodermatitis bovis larvae enter into medulla spinalis during migration may cause paresis as a result of dying larvae.

DRUG INTERACTIONS:

There is no information considering ivermectin incompatibility with other medicines

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE:

Tolerance limit is broad (at most 5 fold in calf-lamb, 10-20 fold in adults. In case of overdose the symptoms related to central nerve system, including mydriasis, depression at various degrees, muscle relaxation, paresis, ataxia, tongue and lip tonus decrease, saliva release, lying on the ground at full length, and coma state are observed. No antidote is known.

WARNINGS ON DRUG RESIDUES IN FOOD:

Withholding Period (WHP): The meat type cattle should not be sent for slaughter before 35 days and the meat type sheep before 42 days following the final drug administration and during the treatment. It could not be administered in milch cow and sheep from which milk is produced for human consumption.

CONTRAINDICATIONS:

Warble factor use during spinal migration is contraindicated. It may cause sensitivity reactions in dogs, especially Collie, and horses. Do not administer intramuscularly and intravenously.

GENERAL WARNINGS:

Consult your veterinary surgeon before using and in case an unexpected effect is observed. Keep out of reach of children. Keep away from food products.

PRECAUTIONS TO BE TAKEN BY THE USER AND WARNINGS FOR VETERINARY SURGEONS:

Do not smoke or eat when administering drug. Avoid contact with drug, wash your hands after administering it.

STORAGE CONDITIONS:

Store in its package in room temperature below 25°C (15 -25°C). Protect from direct sunlight. Shelf life is 3 years as of the production date. By initial use it remains efficient for 6 months as long as complying with asepsis-antisepsis rules, and covered in the way specified before.

DISPOSAL AFTER USE AND WARNINGS FOR NON-TARGET SPECIES:

Be aware of used drug bottles not to be involved in water because ivermectin is toxic considering fish and other aquatic life forms. Do not use in dogs, especially in Collie, because it may cause death. The drug with expired shelf life, which is opened or kept for a long time without complying with storage conditions, should be disposed together with inner package (bottle).

COMMERCIAL PRESENTATION FORM:

Presented to the market as 20, 50 and 100 ml amber vials in cardboard boxes and 250 ml amber vials in plastic boxes.

PLACE AND CONDITIONS OF SALE:

Sold with Veterinary Surgeon's prescription in pharmacies and veterinary surgeries (VSP).

APPROVAL DATE OF PACKAGE INSERT: 11.11.2005

MINISTRY OF AGRICULTURE AND RURAL AFFAIRS

Marketing Authorization Date and No: 11.11.2005/15-021

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

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