PELANGI DAIRY PRODUCT SDN. BHD. (665097-K)
No 46, Lorong Kendi 7, Taman Merak Jaya, 14100 Simpang Ampat,
S.P.S., Pulau Pinang, Malaysia.

PRODUCT LITERATURE

LEVATRON BOLUS

Each bolus contains
Levamisole HCl USP 1 gm

Preservatives
Sodium Benzoate BP 0.15 %

Mode of Administration
Oral administration

Pharmacodynamic
Levamisole stimulate the parasympathetic and symphatic ganglia in susceptible worms. At higher levels, it interferes with nematode carbohydrates metabolism by blocking fumarate reduction and succinate oxidation. The net effect is a paralyzing effect on the worm that is then expelled alive. Levamisole's effects are considered to be nicotine- like in action. Mechanism of action is for its immunostimulationg effects are not well understood. It is believed it restores cell-mediated immune function in peripheral T-lymphocytes and stimulates phagocytosis by monocytes. It is immune stimulating effects appear to be more pronounced in animals that are immune-compromised.

Pharmacokinetic
Levamisole is absorbed from gut after oral dosing and through the skin after dermal application, although bioavailabilities are variable. It is reportedly distributed throughout the body. Levamisole is primarily metabolized with less than 6% excreted unchanged in the urine. Plasma elimination half lives have been determined for several veterinary species: Cattle : 4 - 6 hours, dogs : 1.8 – 4 hours and swine : 3.5 – 6.8 hours. Metabolites are excreted in both the urine and feces.

Indication
Levamisole is indicated for the treatment of nematodes in cattle, sheep, goats, and swine.

Contra-indication
Levamisole is contra-indicated in lactating animals and not indicated for use as dirofilarial adulticide.

Warning /Precaution
Used cautiously, if at all, in animals those are severely debilitated or have significance hepatic impairment. Preferably delay use in cattle that are stressed due to vaccination, dehorning or castration.

Drug Interaction
Other nicotine like compounds (Eg: Pyrantel, morantel, diethyl carbamazine), or cholinesterase inhibitor drugs (Eg; organophosphates, neostigmine) could theoretically enhance the toxic effect of levamisole. The immune reaction and efficacy to Brucella vaccines may enhance by Levamisole. Fatalities have been reported concomitant levamisole and chloramphenicol administration, avoid using these agents together.

Pregnancy and Lactation
Although levamisole is considered relatively safe to use in large animals that are pregnant, use only if the potential benefits outweight the risks. Levamisole is excreted in cow's milk, use with caution in nursing clams.

Side Effects /Adverse Reaction
Adverse effects that may be seen in cattle can include muscle foaming or hyper salivation, excitement or trembling, lip-licking and head shaking. Levamisole may cause a transient excitability in sheep. May cause depression, hyperesthesia and salivation in goats. Swine infected with lung worms may develop coughing or vomiting and may cause salivation or mussle foaming. In dogs, GI disturbance (usually vomiting, diarrhea), neurotoxicity (painting, shaking, agitation or other behavourial changes), agranulocytosis, dypsnea, pulmonary edema, immune-mediated skin eruption (erythroedema, erythema multiforme, toxic epidermal necrolysis and lethargy) and in cats, hypersalivation, excitement, mydriasis and vomiting.

Dosage
For treatment of susceptible nematodes in cattle, sheep, goats and swine:
7.5 mg / kg orally

Sign and Symptoms of Over Dosage and Treatment
Acute levamisole overdosage can result in death due to respiratory failure. Cardiac arrhythmias may also be seen. Symptoms of levamisole toxicity often mimic those of organophosphate toxicity. Symptoms may include hypersalivation, hyperesthesias and irritability, clonic seizures, CNS depression, dyspnea, defecation, urination and collapse.

Treatment :
This effect best treated by supportive means, as animals generally recovers within hours of dosing. Artificial ventilation with oxygen should be instituted until recovery occurs for respiratory failure. If the ingestion was oral, emptying the gut or administering charcoal with cathartics may be indicated.

Withdrawal Period
In cattle, sheep and swine a level of 0.1 ppm has been established for negligible residue in edible tissue

Maximum Residual Period
Muscle, kidney fat (cattle, pig, and sheep) = 10 ug/kg

Packing
Packed in aluminium sheet of 1 bolus.

Pharmaceutical Precaution
Store at room temperature, in a tight, light resistant childproof container.
Expiry date : 3 years from date of manufacture.

Name and Address of Manufacturer
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Malaysian Drug Registration No. : MAL