SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Brand Name: WORMITREX

Generic name: Levamisole HCl

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains.

Levamisole Hydrochloride BP 15mg

3. PHARMACEUTICAL FORM

Oral liquid

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, Calves, Sheep and Goats

4.2 Therapeutic indications

Levamisole is highly effective against all adult roundworms both gastrointestinal (e.g. Haemonchus spp, Cooperia spp, Nematodirus spp, Ostertagia spp, Oesophagostomum spp, Trichostrongylus spp, etc.) and respiratory (e.g. Dictyocaulus spp), as well as against larvae of several species. It is also effective against arrested larvae of a few species (e.g. Ostertagia spp), and against certain eyeworms (e.g. Thelazia spp). Unless delivered using a slow-release device, levamisole (and tetramisole) has no residual effect.

This means that a single administration will kill the parasites present in the host at the time of treatment, but it will not protect the host against re-infestations.

Levamisole is not ovicidal, which means it will not affect eggs already present, but it will affect the larval stage of the worm. To ensure complete eradication of the parasite treat again after remaining eggs have hatched. If this condition persists, a veterinarian should be consulted.

Follow the recommended dosage carefully

4.4 Contraindications

Wormitrex 1.5% Suspension is generally very safe to use but side effects can occur if higher than recommended doses are used or if administered concomitantly with organophosphates. Symptoms include salivation, excitation, colic, mild diarrhea, chronic spasms, sweating, coughing, hyperpnoea and/or vomiting. These symptoms disappear spontaneously.

4.5 Special warnings and precautions for use

- Wash hands after use.
- Do not exceed the above-mentioned dosage.
- Keep out reach of children.

4.6 Interaction with other medicinal products and other forms of interaction

There is a theoretical risk of enhanced toxic effects of levamisole if administered together with other nicotine-like compounds including pyrantel, morantel, diethylcarbamazine etc., or cholinesterase inhibitors such as organophosphates or neostigmine.

4.7 Undesirable effects

None known.

4.8 Overdose

The product is safe for use in poultry at the recommended dosages.

4.9 Withdrawal Periods

- Meat – 14 days
- Milk – 1 day

5. PHARMACOLOGICAL PROPERTIES

Levamisole Hydrochloride is the levoisomer of d1 2, 3, 5, 6-Tetrahydro-6-phenyl-imidazo(2,1-b) thiazole Hydrochloride. Levamisole was found to be active against adult and immature gastro-intestinal and pulmonary nematodes when administered to experimentally infected animals by the oral, subcutaneous, intramuscular or intraperitoneal routes. It is thought to act by paralysing the susceptible parasites, which are then expelled from the alimentary canal. Levamisole is rapidly absorbed following oral, intramuscular, or subcutaneous administration to several animal species. Extensive metabolism occurs with rapid excretion of drug and metabolites, equally distributed between urine and feces in rats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Sodium Methyl Paraben BP
- Sodium Citrate BP
- Citric Acid BP
- Sodium Metabisulphite BP
- Disodium Edetate BP
- Carboxy methyl cellulose
- Tartrazine Yellow
- Purified Water BP

6.2 Incompatibilities

None known

6.3 Shelf life

2 years

6.4 Special precautions for storage

- Store below 300C
- Store in a dry place
- Protect from direct light
- Keep all medicines away from reach of children.

6.5 Nature and contents of container

High-density polypropylene Plastic containers: 125ML, 150ml, 500ml, and 1 litre.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

7.1 Marketing authorization holder

VETCARE KENYA LTD

Address: P.O Box 63405 – 00619 Nairobi

Country: Kenya

7.2 Manufacturing site addresses

VETCARE KENYA LTD

Winsford Park, BabaDogo Road

P.O. BOX 63405 00619 Nairobi, Kenya

7.3 Marketing Authorization Number

Rwanda FDA-VMP-MA-004

7.4 Date of first Authorization/renewal of the Authorization

Date of first Authorization in Rwanda: 22nd March 2022

7.5 Date of revision of the text

11th April 2022