1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

Structure of the Summary of Product Characteristics (SPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Levamisole HCl injection 10%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:

Levamisole Hydrochloride: 100mg;

EDTA-2Na: 0.2mg

Water for injection: add to 1ml

3. PHARMACEUTICAL FORM

Solution for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep and goat

4.2 Indications

Levamisole is antithelmintic used to treat worm infestations in cattle, sheep and goats. It is effective against the following; Lungworms: Dictyocaulus. Stomach worms: Haemonchus, Ostertagia, Trichostrongylus. Intestinal worms: Cooperia, Oesophagoatomum, Bunostomum, Trichostrongylus, Nematodinus, Chabertia.

4.3 Contraindications

Levamisole should not be administered after vaccinations, castration and dehorning.

4.4 Special Warnings for each target species

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 levamisole has been reported in Teladorsagia, Cooperia and Trichostrongylus species in sheep in a number of countries, including the EU. There are reports of resistance in Haemonchus in sheep outside the EU. Resistance to levamisole has been reported in Teladorsagia species in cattle in developed countries such as New Zealand. 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.

In cases of lungworm infections, coughing may persist for a considerable time following successful

treatment due to tissue damage caused by the parasite.

4.5 Special precautions for use

i. Special precautions for use in animals

The drug should not be used for sick or weak animals.

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

Wash splashes from eyes and skin immediately.

If irritation persist, seek medical advice.

Remove any contaminated clothing immediately.

Wash hands and exposed skin after handling this product and before meals.

Levamisole can cause idiosyncratic reactions and serious blood disorders in a very small number of people.

If symptoms such as dizziness, nausea, vomiting or abdominal discomfort are experienced when using this product, or sore mouth, throat or fever occur shortly afterwards, then medical advice should be sought immediately.

4.6 Adverse reactions (frequency and seriousness)

Some adeverse drug reactions have been observed with the use of Levamisole, and they include injection site reactions, vomiting, diarrhea, trembling, difficulty in breathing, drooling, bronchospasm, uncoordinated movement, weakness etc.

4.7 Use during pregnancy, lactation or lay

The product can be safely administered to pregnant or lactating animals However care should be taken when treating heavily pregnant animals and animals under stress from adverse weather conditions, poor nutrition, penning, handling etc.

4.8 Drug interaction

Avoid concomitant use with Chloramphenicol, muscle relaxants, morantel, pyrantel, piperazine, phenylbutazone.

4.9 Dosage and Administration

KACIMISOLE to be administered by subcutaneous injection.

Dosage

As dewormer:

Cattle, Sheep & Goat: 5mg to 7.5mg/kg body weight (0.5ml to 0.75ml/10kg body weight)

As immunostimulant:

3mg to 4mg/kg body weight (0.3ml to 0.4ml/10kg body weight)

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Overdose symptoms include restlelessness, hypersalivation, vomiting, colic, bradycardia, dyspnea, trembling, depression etc.

Nicotine antagonists, anticholinergics, anti-alpha adrenergics and atropine can be used as antidote for overdose.

4.11 Withdrawal period

Meat:

Cattle: 28 days.

Sheep: 15 days.

Do not administer to lactating cattle and sheep for human consumption.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QP52AE01

Pharmacotherapeutic group: Anthelmintics, Imidazothiazoles

5.1 Pharmacodynamic properties

Levamisole hydrochloride is the laevo isomer of dl 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

EDTA-2Na

Water for injection

6.2 Incompatibilities

There's no data available now.

6.3 Special precautions for storage

Keep in a cool dry place, not exceeding 30°C. Protect from light.

6.4 Nature and composition of immediate packaging

Pack size: Glass vials of 100 ml provided with rubber stoppers of bromobutyl and metallic aluminium capsules with FLIP-OFF ring. Containers of 100 ml.

6.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such product

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed accordance to local requirements.

7. Marketing authorization holder

Company name: Hebei New Century Pharmaceutical Co., Ltd.

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8. Marketing authorization number(s)

GMP number: (2022) Veterinary drug GMP No.03034

9. Date of revision of the text

08.2024