

PAZOLE SUSPENSION

(Albendazole, Cobalt Sulphate & Sodium Selenite)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

PAZOLE SUSPENSION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml Contains:

Albendazole 2.500gm

Cobalt Sulphate 0.382gm

Sodium Selenite 0.035gm

3. PHARMACEUTICAL FORM

Oral Suspension.

4. CLINICAL INFORMATION

4.1. Target species

Cattle & Sheep.

4.2. Indications for use specifying the target species

A broad spectrum multi-purpose anthelmintic for the control of mature and developing immature forms of gastrointestinal roundworms, lungworms, tapeworms and adult liver fluke in cattle and sheep. The product is also ovicidal against fluke and roundworm eggs.

In cattle it is active against the following species:

Roundworms: Ostertagia, Haemonchus, Trichostrongylus, Nematodirus, Oesophagostomum, Bunostomum, Cooperia, and Strongyloides spp.

It is usually effective against inhibited larvae of Cooperia and Ostertagia,

Lungworms: Dictyocaulus viviparus,

Tapeworms: Moniezia spp.,

Adult liver fluke: Fasciola hepatica.

In sheep it is active against benzimidazole-susceptible strains of the following species:

Roundworms: Ostertagia, Haemonchus, Trichostrongylus, Nematodirus (Including N. battus), Chabertia and Oesophagostomum

It is usually effective against inhibited larvae of Ostertagia,

Lungworms: Dictyocaulus filaria,

Tapeworms: Moniezia spp.,

Adult liver fluke: Fasciola hepatica.

The product is ovicidal and will kill fluke and roundworm eggs, thus reducing pasture contamination. The product also contains selenium and cobalt as nutritional supplements.

4.3. Contraindications

Do not use in cases of known hypersensitivity to the active substance or to any of the other constituents.

4.4. Special warnings for each target species

Selenium and cobalt are included as nutritional supplements and are not intended to be used therapeutically. Administration of ionophores to lambs has been shown to enhance selenium bioavailability. Concurrent administration of ionophores and Albex 2.5% SC may therefore lead to an increased risk of selenium toxicity.

Cattle suffering from severe lung damage due to heavy lungworm infestation may continue to cough for some weeks after treatment.

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 a different pharmacological class and having a different mode of action should be used.

Resistance to benzimidazoles (which includes albendazole) has been reported in *Teladorsagia Haemonchus*, *Cooperia* and *Trichostrongylus* species in small ruminants in a number of countries, including the EU.

Resistance to albendazole has been reported in *Cooperia* and *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.

4.5. Special precautions for use

Special precautions for safe use in the target species:

Care must be taken not to damage the pharyngeal region when dosing, particularly in sheep. Selenium and cobalt are included as nutritional supplements and are not intended to be used therapeutically. Do not administer other cobalt and selenium supplements concurrently with this product unless specifically advised by your veterinary surgeon. Not to be diluted or mixed with other products.

Avoid the introduction of contamination during use.

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce the risk, dosing programmes should be discussed with a veterinary surgeon.

The product should only be used in areas where deficiencies of selenium and cobalt are likely to occur. In cases of doubt, consult a veterinary surgeon.

Special precautions to be taken by the person administering the product to animals:

Wash hands after use.

Avoid direct contact with the product.

Wear suitable clothing including impermeable rubber gloves.

In the event of accidental eye exposure, flush eye thoroughly with running water. If irritation persists, seek medical attention.

In the event of accidental skin exposure, wash the affected area with soap and water. If irritation persists, seek medical attention.

4.6. Adverse reactions (frequency and seriousness)

None known.

4.7. Use during pregnancy and lactation or lay

Do not dose ewes at the 'fluke and worm' dose rate, (7.5 mg/kg), during tupping or for 1 month after removing the rams. Can be safely used during lactation.

The use of the product in breeding bulls or pregnant cattle is not expected to interfere with their reproductive performance.

4.8. Interaction with other veterinary medicinal products and other forms of interaction

None known

4.9. Dosage and administration route

For oral administration.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Cattle:

Worm dose: For the control of roundworms, lungworms, tapeworms and fluke and roundworm eggs.

Dosage: 7.5 mg albendazole per kg b.w.

Fluke and worm dose: For the additional treatment of adult liver fluke (chronic fascioliasis) in cattle.

Dosage: 10 mg albendazole per kg b.w.

Sheep:

Worm dose: For the control of roundworms, lungworms, tapeworms, and fluke and roundworm eggs.

Dosage: 5 mg albendazole per kg b.w.

Fluke and Worm Dose: For the additional treatment of adult liver fluke (chronic fascioliasis) in sheep.

Dosage: 7.5 mg albendazole per kg b.w.

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

No treatment specified.

4.11. Withdrawal period:

Cattle:

Meat & Offal: 14 days

Milk: 60 hours

Sheep:

Meat & Offal: 5 days

Not to be used in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics; Benzimidazoles and related substances.

ATC-vet code: **QP52AC11**

5.1. Pharmacodynamics properties

A broad spectrum multi-purpose anthelmintic for the control of mature and developing immature forms of gastrointestinal roundworms, lungworms, tapeworms and adult liver fluke in cattle and sheep. The product is also ovicidal against fluke and roundworm eggs. Benzimidazoles bind to nematode tubulin, a protein necessary for the formation and viability of microtubules. This occurs primarily in absorptive intestinal cells resulting in the absence of microtubules in the intestinal cells of the nematode, with the result that these cells cannot absorb nutrients, thus causing a consequent reduction in glycogen and effective starvation of the parasites. Structural differences have been shown to exist between tubulin from mammalian and helminth sources, resulting in the preferential toxicity of albendazole to the helminth and not to the host. Benzimidazoles have also been shown to inhibit the fumarate reductase system of helminths and impair energy production. The selenium and cobalt in this product are trace elements of use as nutritional supplements.

5.2 Pharmacokinetic information

Albendazole has poor water solubility and limited absorption from the gastrointestinal tract (about 50% of the oral dose is absorbed in cattle).

Following absorption, there is rapid first pass metabolism in the liver and the sulphide moiety of albendazole is oxidised to the pharmacologically active sulfoxide, then the sulphone, followed by deacetylation of the carbamate group to form the 2-aminosulphone. Selenium is an essential trace element. After ingestion, it's absorbed in the small intestine and then widely distributed throughout the body, with high concentrations found in the liver and kidneys. The absorption efficiency can vary depending on the form of selenium (e.g., L-selenomethionine is absorbed more efficiently than inorganic selenite). Once in the body, it is metabolized into various compounds, including selenophosphate and selenocysteine, which are the building blocks for selenoproteins. Selenium is primarily eliminated through the kidneys in the urine, but some is also excreted in the feces. The half-life can be quite long, and chronic exposure can lead to accumulation in the body.

Cobalt is an essential component of vitamin B12 (cobalamin), which is crucial for red blood cell formation and neurological function. It's absorbed through the gastrointestinal tract, and the absorption rate can be highly variable and influenced by factors like nutritional status and the specific form of cobalt. After absorption, it is distributed to various tissues, with the highest concentrations found in the liver, kidneys, and spleen. The elimination of cobalt is primarily through the kidneys in the urine, but also through feces. The half-life of cobalt can be prolonged, especially for insoluble forms that may accumulate in the lungs after inhalation.

6. PHARMACEUTICAL INFORMATION

6.1 List of Excipients:

Copper Chlorophyll Complex Sodium
Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Sodium selenite
Cobalt sulfate
Citric Acid Monohydrate (for pH adjustment)
Sodium citrate dihydrate (for pH adjustment)
Xanthan Gum
Povidone 90
Polysorbate 20
Simethicone Emulsion
Propylene Glycol
Water Purified

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after first opening the container: use immediately in 28 days, do not store.

6.4. Special precautions for storage

Store below 25°C.

Protect from light and moisture.

Shake well before use

Keep out of the reach of children.

To be used as directed by the registered veterinary practitioner only.

6.5. Nature and composition of primary conditioning

The product is available in various pack sizes:

- **For 100ml:** HDPE bottles with tightly closed cap.
- **For 500mL:** HDPE bottles with induction-sealed caps.
- **For 1L:** HDPE cans with induction-sealed caps.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF WASTE MATERIALS UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS

Waste materials derived from the use of such products

Medicinal products should not be disposed of via wastewater or household waste.

Use return systems for unused veterinary medicinal products or waste materials derived from such products, in accordance with local requirements and national collection systems applicable to the veterinary medicinal product concerned.

Treated animals should be kept in shelters throughout the treatment period and their droppings should be collected and NOT used for soil fertilization.

7. MARKETING AUTHORISATION HOLDER

Nawan Laboratories (Pvt.) Ltd.

Plots No. 136-138, Sector-15,

Korangi Industrial Area, Karachi-74900, Pakistan.

8. MARKETING AUTHORISATION NUMBER

Reg. No.: 025752

9. DATE OF FIRST AUTHORISATION

Date of Reg: 07-06-2000

10. DATE OF REVISION OF THE TEXT

17-02-2025

MANUFACTURED BY:



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