

ALBAZOL SUSPENSION

(*Albendazole*)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ALBAZOL SUSPENSION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml Contains:

Albendazole 12.5gm

3. PHARMACEUTICAL FORM

Oral Suspension.

4. CLINICAL INFORMATION

4.1. Target species

Cattle.

4.2. Indications for use specifying the target species

Effective against benzimidazole sensitive mature and immature roundworms, including Type II Ostertagia, lungworms, tapeworms and adult liver fluke in cattle.

4.3. Contraindications

Do not use in animals with known hypersensitivity to the active ingredient

4.4. Special warnings for each target species

Care should be taken to avoid the following practices because they increase the risk of developing 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. 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.

4.5. Special precautions for use

Special precautions for use in animals:

Not applicable

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

Avoid direct contact with the skin and eyes. In case of accidental spillage wash the affected area immediately with clean running water. Wear suitable protective clothing including impermeable rubber gloves. Wash hands after use.

4.6. Adverse reactions (frequency and seriousness)

None known.

4.7. Use during pregnancy and lactation or lay

None

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

Do not use at the same time as any other selenium-containing product without consulting a veterinarian.

4.9. Dosage and administration route

Shake well before use. Using standard drenching equipment, administer orally. To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Worm infestations: 7.5 mg albendazole per kg bodyweight (0.9 ml per 15 kg bodyweight).

Worm and Fluke infestation: 10 mg albendazole per kg bodyweight (1.2 ml per 15 kg bodyweight).

Bodyweight (kg) Worm Dose (ml) Worm and Fluke dose (ml)

60	3.6	4.8
120	7.2	9.6
180	10.8	14.4
240	14.4	19.2
300	18.0	24.0
360	21.6	28.8
420	25.2	33.6

Worm Dose: Cattle over 420 kg should be given a further 1 ml for each additional 20 kg bodyweight.

Worm and Fluke dose: Cattle over 420 kg should be given a further 1 ml for each additional 15 kg bodyweight.

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

The product is very well tolerated at the recommended dose rates. In the case of accidental over dosage, depression and anorexia may occur.

4.11. Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

4.12. Withdrawal period:

Meat and offal: 14 days

Milk: 60 hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintic, benzimidazoles and related substances

ATCvet code: **QP52AC11**

5.1. Pharmacodynamic properties

Albendazole acts on parasites by interfering with their energy generating metabolism. It inhibits fumarate reductase, which in turn prevents the generation of mitochondrial energy in the form of adenosine triphosphate (ATP). There is other evidence that the mode of action is the prevention of microtubule polymerization. Differential binding affinities between nematode and mammalian tubulin may explain the selective toxicity of benzimidazoles

5.2. Pharmacokinetic information

In calves, peak plasma levels equivalent to 5.5 micrograms of Albendazole and/or metabolites are achieved 15 hours after the administration of an oral dose of 20 mg radio-labelled Albendazole per kg bodyweight. Twenty-eight percent of the administered dose is excreted in urine during the first 24 hours, and 47% is excreted over a 9-day period. Albendazole is metabolized primarily to its sulfoxide and sulphone, which are excreted mostly through the urine.

6. PHARMACEUTICAL INFORMATION

6.1 List of excipients

Anhydrous citric acid
Colloidal anhydrous silica
Formaldehyde solution 35%
Monopropylene glycol
Macrogol 6000
Polyoxyl sorbate
Potassium sorbate
Xanthan gum
Purified water

6.2 Incompatibilities

None known.

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, 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

HDPE bottles with PP cap and induction seal.

Pack size: 30ml, 150ml, 500ml & 1 Liter

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

Any unused veterinary medicinal products or waste materials derived from such medicinal products should be disposed of in accordance with local requirements and placed in appropriate collection and disposal systems for unused or expired medicinal products.

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.: 014106

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 01-08-1993

10. DATE OF REVISION OF THE TEXT

31-01-2025



136, Sector 15, Korangi Industrial
Area, Karachi-74900, Pakistan.