ALBAWAN 2500 BOLUS
(Albendazole)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ALBAWAN 2500 BOLUS.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Bolus Contains:
Albendazole ……. 2.500gm

3. PHARMACEUTICAL FORM

Bolus.

4. CLINICAL INFORMATION

4.1. Target species

Cattle

4.2. Indications for use specifying the target species

ALBAWAN 2500 BOLUS is indicated for the treatment of infestations with gastrointestinal and pulmonary nematodes, cestodes and trematodes: Avitellina spp. Bunostomum spp. Capillaria spp. Chabertia ovina, Cooperia spp, Dicrocoelium dendriticum Dictyocaulus spp. Dictyocaulus filaria, Fasciola gigantic - adult forms. Fasciola hepatica - adult forms. Fascioloides magna, Gaigeria pachyscelis, Haemonchus contortus, Marshallagia marshalli, Moniezia expansa, Muellerius capillaris, Nematodirus spp, Oesophagostomum spp, Ostertagia ostertagi, Protostrongylus rufescens, Strongyloides papillosus, Thysanosoma actinoides, Trichostrongylus axei, Trichostrongylus colubriformis.

4.3. Contraindications

Do not administer in case of known hypersensitivity to the active substance or to any of the excipients.

4.4. Special warnings for each target species

The following practices, which increase the risk of resistance development and can ultimately lead to treatment inefficiency, should be avoided:
- too frequent and prolonged administration of substances from the same class;
- underdosing, as a result of an incorrect estimation of the animals' weight.

Clinical cases suspected of resistance must be investigated using appropriate tests (e.g., Faecal Egg Count Reduction Test). Where test results suggest resistance to a certain substance, another substance belonging to a different pharmacological class and with a different mechanism of action should be used.

It is recommended that treatments be initiated after performing coproparasitological examinations, corroborated with clinical examinations. If this is not possible, the treatment should be carried out based on local epidemiological information (for the region).

4.5. Special precautions for use

Special precautions for safe use in the target species:

Before administering the product, we must ensure that the animal's oral cavity is free of food debris

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

People with known hypersensitivity to any of the product components should avoid contact with the product. Hands should be washed after administration. In case of accidental ingestion of the product or if allergies occur due to contact with the skin, seek immediate medical advice and show the product leaflet or label. Appropriate protective equipment should be worn when handling the veterinary medicinal product.

4.6. Adverse reactions (frequency and seriousness)

Not known.

4.7. Use during pregnancy and lactation or lay

Albendazole should not be administered to ruminants in the first 45 days of gestation.

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

Not known.

4.9. Dosage and administration route

It is administered orally in the following doses:
- 7.5 mg Albendazole/kg b.w. (1 tablet/ 335 kg b.w.) in a single dose, for infestation with gastrointestinal nematodes, pulmonary nematodes, cestodes
- 10 mg Albendazole/kg b.w. (1 tablet/250 kg b.w.) in a single dose, for infestation with Fasciola hepatica and Fascioloides magna (adult forms)
- 15 mg Albendazole/kg b.w. (1 tablet/ 170 kg b.w.) in a single dose, for severe trematode infestation. In animals kept under conditions of constant exposure to helminthic infestations, the treatment will be repeated 5-6 weeks after the first administration.

To ensure correct dosing, body weight should be determined as accurately as possible to avoid under dosing.

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

The recommended doses must be respected.

4.11. Restrictions and special conditions of use, including restrictions on the use of antimicrobial and antiparasitic veterinary drugs, in order to reduce the risk of resistance development

Medication administered under the control or supervision of the veterinarian

4.12. Withdrawal period:

Meat and Organs: 14 days
Milk: 6 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antihelmintics, benzimidazoles and related substances Vet
ATC code: **QP52AC11**

5.1. Pharmacodynamics properties

The mechanism of toxicity selection and the antihelminthic effect of albendazole are the same as those of other carbamate benzimidazoles - they destroy the function of cytoplasmic microcapillaries and absorb nutrients, inhibit fumarate reductase, acetylcholinesterase, and the use of glycogen, after which the parasites die. Albendazole disrupts energy transfer to the parasites. The use of altered carbon hydrates is associated with the inhibition of tubulin synthesis in intestinal and tegumentary cells - the functional subunit of cytoplasmic microcapillaries, which plays an important role in the transport of nutrients inside the cell. By selectively binding to tubulin, albendazole inhibits its polymerization and the construction of cytoplasmic microtubules in intestinal and tegumentary cells, followed by a disruption of membrane functions, blocking the transport of secretory vesicles, and decreasing the absorption and use of nutrients.

5.2. Pharmacokinetic information

The metabolism of albendazole in mice, rats, sheep, and calves is similar and takes place in the liver - it is first oxidized to the sulfoxide compound and then to sulfone, and subsequently to derivatives (for example, 2-amino-2-propyl-sulfonyl-1Hbenzimidazole), which are found in the blood and tissues. Its concentrations in the bile of sheep are 3-4 times higher than in the blood, therefore, its high reactivity against adult Fasciola spp. From the blood, albendazole sulfoxide passes (by passive diffusion) into the fluids of the digestive tract. It is excreted mainly through urine and less with bile.

6. PHARMACEUTICAL INFORMATION

6.1 Excipients

Corn starch,
Magnesium stearate,
Calcium phosphate dihydrate,
Sodium starch glycolate,
Lactose monohydrate,
chlorophyllin.

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.

6.4. Special precautions for storage

Store below 25°C in a dry place.
Protect from light and moisture.
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

Alu/PVC blister in Unit carton
Pack size: 20's, 40's & 100's

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.: 035072

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 13-12-2004

10. DATE OF REVISION OF THE TEXT

17-02-2025

MANUFACTURED BY:

NAWAN LABORATORIES (PVT) LTD. | 136, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan.