ALBAZOL-S BOLUS
(Albendazole)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ALBAZOL-S BOLUS.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Bolus Contains:
Albendazole …… 152mg

3. PHARMACEUTICAL FORM

Bolus /Tablet

4. CLINICAL INFORMATION

4.1. Target species

Sheep and Goats.

4.2. Indications for use specifying the target species

Control of parasitic infestations in sheep and goats caused by: - gastrointestinal nematodes of the genera Haemonchus, Chabertia, Trichostrongylus, Ostertagia, Bunostomum, Cooperia, Nematodirus, Oesophagostomum and Strongyloides; - lungworm (Dictyocaulus filaria); - adult forms of large (Fasciola hepatica) and small (Dicrocoelium lanceatum) flukes; - tapeworms of the genus Moniezia.

4.3. Contraindications

ALBAZOL-S BOLUS should not be given to sheep and goats during the breeding season and for one month after the breeding rams and goats have been removed.

4.4. Special warnings for each target species

When administering the medicine, care must be taken not to damage the pharynx.
The practices listed below increase the risk of resistance and may lead to treatment ineffectiveness and should be avoided:

- excessive and repeated use of anthelmintics of the same class over a long period of time
- underdosing, which may be due to underweight determination, medication administration errors or uncalibrated dosing applicators (if used).
- In clinical cases where anthelmintic resistance is suspected, further investigation using appropriate tests (e.g. egg reduction test/ FECR test) should be performed. In cases where test results indicate resistance to a particular anthelmintic, an anthelmintic from a different pharmacological class with a different mode of action should be used.

4.5. Special precautions for use

Special precautions for safe use in the target species:

Albendazole is not recommended for treating acute fluke infection due to its lower effectiveness on immature stages of fluke.

The feces of treated animals should be collected regularly for a few days after administration and destroyed harmlessly.

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

Wear rubber gloves when using.
Wash your hands after use.

4.6. Adverse reactions (frequency and seriousness)

In individual animals that are heavily infested with lungworms and have damaged lungs as a result, a cough may occur after treatment, lasting for several days. If you notice any side effects with this medicine, inform the competent pharmacovigilance authority and the marketing authorisation holder immediately.

4.7. Use during pregnancy and lactation or lay

Pregnancy: The use of therapeutic doses of ALBAZOL-S BOLUS is harmless in pregnant sheep and goats. To prevent the possible teratogenic effect of albendazole on the fetus, it is not recommended to administer it to sheep and goats during the breeding season and for one month after the removal of breeding rams and goats.
Lactation: Albendazole can be administered during lactation.

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

Not known.

4.9. Dosage and administration route

The tablets are administered orally without prior preparation of the animal.

For the control of whipworms, gastrointestinal and pulmonary nematodes and cestodes, it is administered once (5 mg albendazole per 1 kg of body weight):

- up to 30 kg body weight: 1 tablet of 152 mg
- up to 45 kg body weight: 1.5 tablets of 152 mg each
- up to 60 kg body weight: 2 tablets of 152 mg
- up to 75 kg body weight: 2.5 tablets of 152 mg each
- up to 90 kg body weight: 3 tablets of 152 mg each

To control small flies, apply a smaller or larger dose twice, 1 to 2 weeks apart.

When treating several animals at the same time, they should be grouped according to body weight and the correct dose determined to avoid under- or overdosing.

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

In healthy animals, an overdose of the drug in a dose five times higher than the recommended dose rarely causes side effects.

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:

Sheep:
- meat and offal: 10 days
- milk: 5 days

Goats:
- meat and offal: 10 days
- milk: 7 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Benzimidazoles and related substances.
ATC vet code: **QP52AC11**

5.1. Pharmacodynamics properties

Albendazole belongs to the group of benzimidazoles. It has a broad spectrum of activity and is active against all important gastrointestinal and pulmonary nematodes, such as *Fasciola hepatica*, *Dicrocoelium lanceatum*, and strobilus tapeworms of the genus *Moniezia*. Albendazole has a wide safety margin.
Albendazole is an anthelminthic of the benzimidazole group. Albendazole, like other anthelminthics of the benzimidazole group, acts primarily by binding to nematode tubulin. More specifically, benzimidazoles bind to dimeric tubulin, which in turn prevents tubulin polymerization during microtubule formation. At mammalian body temperature, benzimidazoles act selectively, with greater effect on nematode tubulin than mammalian tubulin.
The most effective in this group are poorly soluble compounds, which include albendazole. As a solid deposit, it remains in the intestine for a longer period. Since the solid form dissolves slowly, the effective concentration is maintained in the plasma and intestine for a longer period, thus increasing the effectiveness of this compound on immature and mature stages of nematodes.

Considering the reduced egg count and the fact that the hatchability of fluke eggs in treated animals is reduced, it is likely that surviving flukes will have reduced reproductive capacity. Consequently, the use of albendazole in animals will prevent contamination of the pasture. This reduces the possibility of reinfection.

Albendazole, used in sheep, shows efficacy against mature and immature stages of economically important gastrointestinal and pulmonary parasites such as *Fasciola hepatica*, *Dicrocoelium lanceatum*, and also tapeworms. It is also effective against eggs of whipworms and nematodes. Albendazole is effective against the following parasites:
- gastrointestinal nematodes from the genera *Haemonchus*, *Chabertia*, *Trichostrongylus*, *Ostertagia*, *Bunostomum*, *Cooperia*, *Nematodirus*, *Oesophagostomum* and *Strongyloides*;
- lungworm (*Dictyocaulus filaria*);

- mature forms of the large (*Fasciola hepatica*) and small fluke (*Dicrocoelium lanceatum*);
- Tapeworms of the genus *Moniezia*.

Resistance Worldwide, the increased use of anthelminthics stimulates the selection and development of resistant parasite strains and is expected to be a major problem in the future. For this reason, slow rotation of anthelminthics, e.g. at 1 to 2-year intervals, is recommended.
In general, when parasites develop resistance to just one active ingredient from the benzimidazole group, they are also resistant to all other active ingredients from this group.

5.2. Pharmacokinetic information

Absorption Absorption from the stomach and intestines is very good (in cattle, 50% of an orally administered dose is absorbed from the intestines). In ruminants, the rumen is a reservoir of the active substance. The active substance is released from the rumen gradually. Albendazole is released from the rumen slowly and completely over 3 to 4 days, with a maximum on the first day. Absorption from the rennet is faster. In cattle, the highest blood level is reached within 15 to 24 hours after oral administration of albendazole, and in sheep after 15 hours.
Albendazole is primarily metabolized to sulfoxide and sulfonate derivatives, which also exert an antiparasitic effect.
Distribution Oral administration results in low plasma levels of albendazole because it is rapidly metabolized in the liver. Metabolites in the gastrointestinal tract, as well as those in the blood, potentiate the effect of albendazole on gastrointestinal parasites. The highest albendazole residues were detected in the liver, kidneys, muscles, and fat.
Studies in cattle indicate that high concentrations of albendazole (up to 5.5 micrograms/ml) were achieved within 15 to 24 hours after oral administration of a 20 mg/kg dose. In sheep, the highest concentration (up to 3.7 micrograms/ml) was achieved within 15 hours after administration of a 16 mg/kg dose.
Metabolism It is assumed that the main anthelminthic effect of albendazole is based on its metabolic products. Since the concentration of albendazole and its metabolites in plasma is maintained for 3 to 4 days, a comparison of the effect after single or repeated administration of the same doses has shown that the administration interval should be 24 or even 48 hours. In both animal species, the half-life of albendazole is about 10 hours.
In sheep, after oral administration of albendazole at a dose of 5 mg/kg body weight, no albendazole sulfone or sulfoxide could be detected in rumen fluid with a precision of 0.3 to 0.05 micrograms/ml. Administration of albendazole at a dose of 10 mg/kg body weight resulted in a concentration of 0.7 micrograms/ml in rumen fluid after 4 hours.
Albendazole can be detected in low concentrations in the cap as early as 10 minutes after administration, while its metabolites (sulfones and sulfoxides) can be detected only after 4 hours. In the liquid contents of the cap, the highest concentration of albendazole is reached within 8 to 16 hours and persists for up to 96 hours after administration of the drug, although only in very low concentrations (0.01 micrograms/ml).
Elimination
Albendazole is excreted mainly in the urine as sulfoxide and sulfone derivatives (51% in sheep and 47% in cattle) within 120 hours of administration. Small amounts of metabolites are excreted in the faeces and milk within 48 hours in sheep and 72 hours in cattle.

6. PHARMACEUTICAL INFORMATION

6.1 Excipients

Calcium carbonate
Corn starch

Gelatin
Magnesium stearate

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 within 28 days, do not store.

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, 50'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.: 014104

9. DATE OF FIRST AUTHORISATION
Date of Reg.: 01-08-1993

10. DATE OF REVISION OF THE TEXT
17-02-2025