ALBAZOL-C BOLUS
(Albendazole)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ALBAZOL-C BOLUS.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Bolus Contains:
Albendazole…… 600mg

3. PHARMACEUTICAL FORM

Bolus/Tablet

4. CLINICAL INFORMATION

4.1. Target species

Calves, Sheep & Goats

4.2. Indications for use specifying the target species

This Product is recommended for the prevention and treatment of the following parasites:
- Nematodes: Haemonchus spp., Ostertagia spp., Trichostrongylus spp., Cooperia spp., Nematodirus spp., Gaygeria pachyschelis, Marshallagia marchalli, Oesophagostomum spp., Chabertia ovina, Dictyocaulus filaria, Protostrongylus rufescens, and Muellerius capillaris.
- Cestodes: Moniezia expansa and Avitellina spp.
- Trematodes: Fasciola hepatica, Fasciola gigantica, Fascioloides magna, and Dicrocoelium dendriticum.

4.3. Contraindications

Do not administer to pregnant animals during the first half of their pregnancy.
Do not administer doses higher than 15 mg/kg of body weight to heifers or 10 mg/kg of body weight to sheep and goats that are in the second half of their pregnancy.
Do not administer in cases of known hypersensitivity to albendazole.

4.4. Special warnings for each target species

Do not administer to pregnant animals in the first half of their pregnancy.
Do not administer doses higher than 15 mg/kg of body weight to heifers and 10 mg/kg of body weight to sheep and goats that are in the second half of their pregnancy

4.5. Special precautions for use

Special precautions for safe use in the target species:

Not applicable

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

Wash hands thoroughly after using the medicine

4.6. Adverse reactions (frequency and seriousness)

None have been reported. If you notice any serious or other adverse effects not mentioned in the package leaflet, please inform your veterinarian

4.7. Use during pregnancy and lactation or lay

Do not administer to pregnant animals in the first half of their pregnancy.
- Do not administer doses higher than 15 mg/kg of body weight to heifers and 10 mg/kg of body weight to sheep and goats that are in the second half of their pregnancy.
- Albendazole has no adverse effects on the fertility of male animals.

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

Not known.

4.9. Dosage and administration route

Administer orally.

Calves:
- For gastrointestinal nematodes, pulmonary nematodes, and tapeworms: 7.5 mg/kg body weight (1 tablet per 80 kg body weight).
- For chronic hepatic fascioliasis (liver fluke): 10 mg/kg body weight (1 tablet per 60 kg body weight). A dose of 15 mg/kg body weight is recommended for very severe infections.

Sheep and Goats:
- For gastrointestinal nematodes, pulmonary nematodes, and tapeworms: 3.8 mg/kg body weight (1/4 of a tablet per 40 kg body weight).
- For pulmonary nematodes (Muellerius capillaris and Protostrongylus rufescens) and chronic hepatic fascioliasis (Fasciola hepatica adult form): 7.5 mg/kg body weight (1/2 of a tablet per 40 kg body weight).
- For hepatic fascioliasis caused by the parasite Dicrocoelium dendriticum: 15 mg/kg body weight (1 tablet per 40 kg body weight)

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

None.

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:

Calves:
- Meat and edible offal: 14 days.

Sheep and Goats:
- Meat and edible offal: 10 days.
- Milk: 132 hours.

5. PHARMACOLOGICAL PROPERTIES

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

5.1. Pharmacodynamics properties

Albendazole is a broad-spectrum anthelmintic that acts against mature and immature forms of gastrointestinal nematodes, pulmonary nematodes, certain tapeworms (including larval forms), and trematodes. This Product has a strong ovicidal action, which leads to the death of nematode and fluke eggs. The safety index of albendazole is 10 times the recommended therapeutic dose. No adverse effects on the reproductive capacity of male animals were observed with this product.

5.2. Pharmacokinetic information

After oral administration, albendazole is absorbed from the gastrointestinal tract and extensively metabolized in the liver. Although an enterohepatic metabolic cycle is observed, its effect on the elimination rate from tissues appears to be small. Its main metabolite, albendazole sulfoxide, has anthelmintic activity and a plasma half-life of approximately 8.5 hours, and it is excreted in the urine along with other metabolites.

6. PHARMACEUTICAL INFORMATION

6.1 List of Excipients

Potato Starch
Sodium Starch Glycolate (type A)
Povidone K30
Cellulose, Microcrystalline
Magnesium Stearate
Calcium hydrogen phosphate, dihydrate
Tartrazine
Brilliant Blue

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.: 014105

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 01-08-1993

10. DATE OF REVISION OF THE TEXT

17-02-2025