

PACKAGE LEAFLET

For animal treatment only

ALBENDAZOLE/ PROVET 300mg
tablets 300mg anthelmintic for calves, sheep, goats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:

PROVET S.A.

120, Eleftherias Avenue, Eleousa, Zitsa, 45500 Ioannina, Greece

Tel.: +30 2105508500, +30 2105575770-3

E-mail: vet@provet.gr

Manufacturer responsible for batch release:

PROVET S.A. (FACTORY)

Nikiforou Foka & Agion Anargyron, Thesi Vrago,

193 00 Aspropyrgos, Attiki, Greece

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALBENDAZOLE/ PROVET

Tablets

Albendazole 300 mg/tab

for Calves, sheep, Goats

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each tablet contains:

Active substance: Albendazole 300 mg

Excipients: Povidone K30, Microcrystalline cellulose, Sodium starch glycolate, Talc, Magnesium stearate, Colloidal silicon dioxide, Hydrogenated castor oil, Tartrazine, Lactose, Alcohol, Purified water

4. INDICATIONS

Albendazole is recommended for the prevention and treatment of gastrointestinal roundworms, lungworms, tapeworms and chronic fascioliasis of calves, sheep and goats.

Albendazole is an anthelmintic with a very wide spectrum, effective against both mature and immature stages of various intestinal and pulmonary nematodes and some major economic importance platyhelminths (cestodes and trematodes). Furthermore, albendazole is an effective ovicidal of the gastrointestinal nematodes' eggs and those of *Fasciola hepatica*. Specifically, albendazole is effective against the following parasites:

NEMATODES *Haemonchus* spp., *Ostertagia* spp., *Trichostrongylus* spp., *Cooperia* spp., *Nematodirus* spp., *Gaygeria pachyschelis*, *Marshallagia marshalli*, *Oesophagostomum* spp., *Chabertia ovina*, *Dictyocaulus filaria*, *Protostrongylus rufescens*, *Muellerius capillaris*

CESTODES *Moniezia expansa*, *Avitellina* spp.

TREMATODES *Fasciola hepatica*, *Fasciola gigantica*, *Fascioloides magna*, *Dicrocoelium dendriticum*.

Albendazole is also a pesticide against immature stages of cestodes.

5. CONTRAINDICATIONS

It is recommended not to use in young female goats intended for breeding.

6. ADVERSE REACTIONS

None known

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction)

- common (more than 1 but less than 10 animals in 100 animals treated)

- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Calves, Sheep, Goats

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Administer per os. Administer to animals that have not previously eaten.

Dosage varies according to the kind of worm and the animal species.

Calves

- 7.5 mg/ kg of b.w. (2 tablets of ALBENDAZOLE tablets 300/ 80 kg of b.w.) against gastrointestinal roundworms, lungworms and tapeworms.

- 10 mg/ kg of b.w. (2 tablets of ALBENDAZOLE tablets 300/ 60 kg of b.w.) against chronic fascioliasis due to *Fasciola hepatica*. In acute and severe cases dosage of 15 mg/ kg of b.w. is recommended.

Tablets are administered per os either by hand or with an administration gun.

Sheep-Goats

- 3.8 mg/ kg of b.w. ($\frac{1}{2}$ tablet of ALBENDAZOLE tablets 300 per animal up to 40 kg of b.w.) against gastrointestinal roundworms.

- 7.5 mg/ kg of b.w. (1 tablet of ALBENDAZOLE tablets 300 per animal up to 40 kg of b.w.) against lungworms.

- 10 mg/ kg of b.w. ($1\frac{1}{3}$ tablet of ALBENDAZOLE tablets 300 per animal up to 40 kg of b.w.) against fascioliasis due to *Fasciola hepatica*.

- 15 mg/ kg of b.w. (2 tablets of ALBENDAZOLE tablets 300 per animal up to 40 kg of b.w.) against fascioliasis due to *Dicrocoelium dendriticum*.

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD(S)

Calves: Meat & offal: 6 days

Sheep-Goats: Meat & offal: 10 days

Milk: 5.5 days

Do not administer to cows producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the box. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Do not administer to pregnant animals during the first half of pregnancy.

Do not administer doses greater than 15 mg/ kg of b.w. in heifers and 10 mg/ kg of b.w. in sheep and goats during the second half of pregnancy.

Do not administer in cases of known hypersensitivity to albendazole.

Albendazole has no effect on the reproductive system of male animals.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

MAY 2013

15. OTHER INFORMATION

PACKAGE

Box with 50 tablets in blister

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorization holder.

under veterinary medical prescription

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN