

PACKAGE LEAFLET

For animal treatment only

ALBENDAZOLE/ PROVET 10%,
oral suspension anthelmintic for Cattle, Sheep and Goats

1. NAME AND ADDRESS OF THE MARKETING AUTHORIZATION HOLDER AND OF THE MANUFACTURING AUTHORIZATION 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 & Ag.Anargyron, Thesi Vrago,

193 00 Aspropyrgos, Attiki, Greece

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALBENDAZOLE/PROVET

oral suspension

Albendazole 10% w/v

Cattle, Sheep and Goats

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each 1 ml contains:

Active substances: Albendazole 100 mg

Excipients: Aluminium magnesium silicate, Carmellose sodium, Glycerol, Polysorbate 80, Sorbitan laurate, Sorbic acid, Benzoic acid, Simeticone, 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*, *Strongyloides* spp., *Marshallagia marchalli*, *Oesophagostomum* spp., *Chabertia* spp., *Dictyocaulus* spp., *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(s))

- 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

Cattle, Sheep, Goats.

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

Administered per os at the following dose rates according to the kind of worm.

- 3.8 mg/kg b.w. (1,5 ml ALBENDAZOLE oral susp. 10% / 40 kg of b.w.) against gastrointestinal roundworms.
- 7.5 mg/kg b.w. (3 ml of ALBENDAZOLE oral susp. 10% / 40 kg of b.w.) against lungworms.
- 10 mg/ kg of b.w. (4 ml of ALBENDAZOLE oral susp. 10% / 40 kg of b.w) against fascioliasis due to *Fasciola hepatica*.
- 15 mg/ kg of b.w. (6 ml of ALBENDAZOLE oral susp. 10% / 40 kg of b.w) against fascioliasis due to *Dicrocoelium dendriticum*.

In acute and severe cases dosage of 15 mg/kg of b.w. is recommended.

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD

Cattle: Meat & offal: 7 days.

Cattle: Milk: 84 hours

Sheep and goats: Meat & offal: 7 days.

Sheep and goats: Milk: 4 days.

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 container. 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

AUGUST 2021

15. OTHER INFORMATION

PACKAGE

Vials of 50 ml, 100 ml, 200 ml, 500 ml, 1 L, 2.5 L and 5 L.

Not all pack sizes may be marketed.

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