

PACKAGE LEAFLET

For animal treatment only

THIABENDAZOLE/ PROVET tablets Tablets of thiabendazole Cattle, 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 & Ag.Anargyron, Thesi Vrago,

193 00 Aspropyrgos, Attiki, Greece

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

THIABENDAZOLE/ PROVET

Tablets

2000mg/tab

Thiabendazole

Cattle, Sheep, Goats

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each tablet contains:

Active substance: 2 g Thiabendazole (2-(4-Thiazolyl)-benzimidazole)

Excipients: Cellulose microcrystalline, Hydrogenated castor oil, Sodium starch glycollate, Sodium lauryl sulfate, Magnesium stearate, Povidone (Polyvinylpyrrolidone), Lactose, Polysorbate 80, Starch maize, Alcohol

4. INDICATIONS

It is recommended for the treatment of parasitic infestations of animals caused by mature and immature stages of gastrointestinal and pulmonary roundworms. In severe cases of pulmonary strongyliasis, use double the dose indicated for gastrointestinal strongyliasis. It is also recommended for the treatment against *hepatic dicrocoeliosis*.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Prolonged and improper dosage may lead to the development of resistant parasitic strains especially in *Haemonchus contortus*, *Ostertagia circumcincta* and *Trichostrongylus colubriformis*. This is avoided by using the appropriate therapeutic dose, at regular intervals, and the alteration of the chemical group of anthelmintics.

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

It is administered per os by hand or with a balling gun. They can be also crushed and dissolved in water.

ANIMAL SPECIES	BODY WEIGHT	NUMBER OF TABLETS			
		ROUTINE WORMING	SEVERE PARASITISM	LUNGWORMS	DICROCOELIOSIS
Lambs-Kids	under 25 kg	½	1	1	2 ½
Sheep-Goats	over 25 kg	1	1 ½	2	4
Rams-Goat	over 50 kg	1 ½	2 ½	3	5
Cattle	per 30 kg	1	-	2	-

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIODS

Meat: 5 days

Milk: 3 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a cool and dry place.

Shelf-life of the veterinary medicinal product as packaged for sale: 60 months

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

Thiabendazole is incompatible with products containing copper and cobalt salts. It is synergistic with other anthelmintics and especially with bithionol sulfoxide.

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

MARCH 1989

15. OTHER INFORMATION

PACKAGES

Box of 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