PACKAGE LEAFLET

For animal treatment only

RAFOXANIDE/ PROVET

Tablets of rafoxanide for sheep

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

RAFOXANIDE/ PROVET
Tablets
300mg/tab,
Rafoxanide
for sheep

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each tablet contains:
Active substance: 300 mg Rafoxanide
Excipients: Aerosil 200, Cellulose microcrystalline, Primojel, Sodium lauryl sulfate, Polysorbate 80 Magnesium stearate, Povidone, Starch maize, Sodium hydroxide, Lactose, Alcohol

4. INDICATIONS

RAFOXANID/PROVET tablets 300 is indicated for the treatment of mature and immature stages of liver flukes (*Fasciola hepatica* and *Fasciola gigantica)* of sheep. It is also effective against mature and immature stages of all strains of *Haemonchus contortus*, as well as all the larvae stages of the sheep nasal bot fly *(Oestrus ovis)*.

5. CONTRAINDICATIONS

Do not administer to exhausted animals with hepatic insufficiency.

6. ADVERSE REACTIONS

There are no side effects or toxicity reported if the product is used as directed to healthy animals.

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

Sheep

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

Administer per os.
Sheep: 7.5 mg rafoxanide/ kg of b.w. (1 tablet of 300 mg **RAFOXANIDE/PROVET tabets 300**/ 40 kg of b.w.).

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIODS

Sheep: Meat: 42 days
Not authorised for use in ewes producing milk for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in ambient conditions.
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

Do not exceed therapeutic doses greater than 7.5 mg/ kg of b.w. and do not administer to animals with poor health condition. There is no antidote in case of toxicosis and treatment is symptomatic with the administration of methionine and B complex vitamins.

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

DECEMBER 2019

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