

PACKAGE LEAFLET

For animal treatment only

OPTIPRIME

powder for oral solution of sulfadiazine and trimethoprim for lambs and kids

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

OPTIPRIME

powder for oral solution

sulfadiazine and trimethoprim

(1g+200mg)/10g

for lambs and kids

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

10 g of powder contain:

Active substances:, 10g Sulfadiazine , 200mg Trimethoprim

Excipients: Cetrимide, Lactose monohydrate

4. INDICATIONS

OPTIPRIME powder for oral solution is indicated for the treatment of the bacterial diarrhoea of lambs and kids.

5. CONTRAINDICATIONS

Do not administer to ruminating animals with a functional rumen.

6. ADVERSE REACTIONS

Sulfonamides' toxicity is relatively small. Rarely and after long term high dosing administration, may the following occur: hypersensitivity reactions (urticaria, hemolytic anemia, skin rash), kidney damages, gastrointestinal disturbances (nausea, vomiting), aplastic anemia, granulocytopenia, thrombocytopenia, hepatitis and jaundice.

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

Lambs, Kids

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

Administer per os.

The recommended dose of the product is 125mg OPTIPRIME/ kg of b.w. every 12 hours (5g OPTIPRIME/ 40kg of b.w. every 12 hours). Treatment should be continued for 5 days.

The product can be administered diluted in the drinking water or the milk to each animal individually.

9. ADVICE ON CORRECT ADMINISTRATION

Wash hands after use

10. WITHDRAWAL PERIOD(S)

Lambs-Kids: Meat and offal's : 5 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 25°C.

Shelf-life of the veterinary medicinal product after dilution, according to instructions: 24 hours

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 sulfonamides concurrently with procaine penicillin and calcium ions. In simultaneous administration with antioxidants, their bioavailability is reduced. Sulfonamides may enhance the action of furosemide, thiazide diuretics, carbonic anhydrase inhibitors and sulfonyleureas.

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 2011

15. OTHER INFORMATION

PACKAGES

Box of 250 g

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