

OPTIPRIME tablets
of sulfadiazine and trimethoprim for lambs, kids

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

OPTIPRIME

Tablets

Sulfadiazine+Trimethoprim (1000 + 200) mg/tablet

For Lambs, Kids

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Each tablet contains:

Active substances: 1000 mg Sulfadiazine, 200 mg Trimethoprim

Excipients: Microcrystalline cellulose, Sodium starch glycolate, Povidone, Sodium lauryl sulfate, Magnesium stearate, Polysorbate 80, Lactose, Alcohol

4. INDICATION(S)

OPTIPRIME tablets can be used per os for the treatment of bacterial diarrhea of lambs and kids caused by microorganisms susceptible to the combination of sulfadiazine-trimethoprim.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to sulfonamides, hepatic or renal insufficiency.

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

Lambs, Kids

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

Administer orally.

Lambs-Kids: 1 tablet per 40 kg of b.w. daily for 4-5 days.

OPTIPRIME® tablets can be administered entirely by hand or with a catheter or dissolved in water. Preferably the daily dose should be divided into two equal parts, administered in the morning and in the evening.

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD

Lambs-Kids:

Meat and offal: 4 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a cool and dry place protected from light.

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

12. SPECIAL WARNINGS

None

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

OCTOBER 2010

15. OTHER INFORMATION

PACKAGE

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 REACH AND SIGHT OF CHILDREN