

PACKAGE LEAFLET

For animal treatment only

OPTIPRIME piglet suspension of sulfadiazine and trimethoprim for pigs (piglets)

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.

Ioannina, Greece

Tel.: +30 2105508500

+30 2105575770-3

E-mail: vet@provet.gr

Manufacturer responsible for batch release:

PROVET S.A. (FACTORY)

Thesi Vrago, GR-193 00 Aspropyrgos, Attiki, Greece

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

OPTIPRIME piglet suspension

Oral suspension

Sulfadiazine+Trimethoprim (45,5+9,1) mg/ml

For pigs(piglets)

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

100 ml of suspension contain:

Active substances:

Sulfadiazine 4.55 g

Trimethoprim 0.91 g

Excipients: Bevaloid 35, Glycerol, Xanthan gum, Chlorocresol, Purified water

4. INDICATION(S)

OPTIPRIME piglet suspension is indicated for the treatment of neonatal scours in piglets, as well as for infections caused by Gram positive and negative bacteria, that are susceptible to the combination of sulfadiazine and trimethoprim.

5. CONTRAINDICATIONS

Do not administer to animals with known hypersensitivity to sulfonamides, hepatic or renal insufficiency.

6. ADVERSE REACTIONS

Hypersensitivity reactions, renal damage (from crystallization of sulfonamide), alteration of the natural flora and gastrointestinal disturbances.

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

Pigs (piglets)

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

Administer per os 15 mg of combined active ingredient/ kg/ 12 hours equivalent to 1.1 ml/ 2 kg b.w. (one meter dose of the dispenser in which the suspension is supplied) per day. The treatment should continue for up to 2 days after symptoms have resolved and should not last more than 5 days in total.

Administration is done by placing the extension tube of the dispenser on the back of the piglet's tongue. In order to ensure accurate doses the bottle must be held upright. The dispenser may remain fitted to the bottle during the entire course of the treatment. Alternatively the dispenser may be removed from the bottle, which should then be recapped. To clean the dispenser, pump tap water through it and then store it in a clean place.

9. ADVICE ON CORRECT ADMINISTRATION

Wash hands after use.

10. WITHDRAWAL PERIOD(S)

Meat and edible tissues: 4 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a dry and cool place protected from light.

Store below 25°C.

Shelf life after the first opening of the container: 1 month

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

Do not use sulfonamides concurrently with procaine penicillin and calcium ions. In concurrent administration with antioxidants, their bioavailability is reduced. Sulfonamides may enhance the action of furosemide, thiazide diuretics, carbonic anhydrase inhibitors and sulfonylurea.

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**
08.04.2013

15. OTHER INFORMATION

PACKAGE

Bottle of 200 ml

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