PACKAGE LEAFLET

For animal treatment only

OPTIPRIME medicated premix 40%
of sulfadiazine and trimethoprim for pigs

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
Medicated premix 40%
Sulfadiazine+Trimethoprim (33,33% + 6,67%) w/w
for pigs

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

100 g of product contain:
Active substance:

Sulfadiazine	33.33 g
Trimethoprim	6.67 g

Excipient: Calcium carbonate

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

OPTIPRIME premix 40% is indicated for the treatment of the bacterial diarrhea of pigs.

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

Pigs

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

The average daily dose is 30 mg of combined active ingredients per kg of b.w. which is equivalent to 3 g OPTIPRIME premix 40% per 40 kg of b.w. daily or 1.5 kg OPTIPRIME premix 40% per tonne of feed for 5 days. OPTIPRIME premix 40% is mixed in the feed prior to its preparation. It is advisable to first mix the recommended quantity of the premix with a smaller amount of the feed, before mixing it with the final feed. OPTIPRIME premix 40% can also be added or mixed with wet feed.

9. ADVICE ON CORRECT ADMINISTRATION

Wash hands after use.

10. WITHDRAWAL PERIOD(S)

Meat and edible tissues: 5 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a cool and dry place protected from light in ambient temperature.
Shelf life of the veterinary medicinal product after mixing in the feed: 3 months
Do not use this veterinary medicinal product after the expiry date which is stated on the box or sack. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Not required.

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

15.10.2010

15. OTHER INFORMATION

PACKAGE
Box of 5 kg
Sac of 20 kg

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