

PACKAGE LEAFLET

For animal treatment only

NEOMYVET 70% powder for oral solution of neomycin for pigs, poultry

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

NEOMYVET

Powder for oral solution

70% Neomycin

for Pigs, Poultry

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 g of product contains:

Active substance: Neomycin sulfate (equivalent to 490 mg Neomycin base) 700 mg

Excipient: Sucrose powder

4. INDICATIONS

For the prevention and treatment of bacterial enteritis of pigs and poultry, caused by microorganisms susceptible to neomycin.

5. CONTRAINDICATIONS

None known

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

Pigs, Poultry

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

The oral administration of daily dose of neomycin sulfate for pigs and poultry is 11 mg/ kg of b.w.

This dose is ensured by diluting the product in the drinking water at the following rates:

In water:

In order to calculate the administered in the drinking water dose of **NEOMYVET** powder for oral solution 70% for pigs and poultry, one must multiply the kilos of body weight 16 times and divide the product by 1000. The result expresses the quantity of **NEOMYVET** powder for oral solution 70% in grams that must be dissolved in the water. The correct dose is added to the drinking water that is to be consumed by poultry within the next 12 hours. The addition of **NEOMYVET** powder for oral solution 70% in the drinking water must be done daily. During the course of treatment there should not be other water sources available.

For the prevention of bacterial enteritis it is recommended the administration of **NEOMYVET** powder for oral solution 70% for at least 5 to 10 days, when the danger is more eminent. For the treatment of bacterial enteritis the product is administered for 3-5 days. If there is no improvement within 3 days of treatment, the diagnosis should be re-evaluated.

9. ADVICE ON CORRECT ADMINISTRATION

If there is no improvement within 3 days of treatment, the diagnosis should be re-evaluated and the antibacterial agent altered. Should the diarrhea be complicated by other infectious agents, administer systematic antibacterial treatment.

10. WITHDRAWAL PERIODS

Pigs: 0 days

Broilers: 1 day

Poultry (turkeys, ducks): 0 days

Eggs: 0 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store at temperatures below 25 °C.

Shelf-life after dilution in the drinking water according to directions : 24 hours

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

12. SPECIAL WARNING(S)

If there is no improvement within 3 days of treatment, the diagnosis should be re-evaluated and the antibacterial agent altered. Should the diarrhea be complicated by other infectious agents, administer systematic antibacterial treatment.

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

JANUARY 2008

15. OTHER INFORMATION

PACKAGE

Plastic container of 500 g

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