

PACKAGE LEAFLET

For animal treatment only

NEO-OXYVET

powder for oral solution of oxytetracycline and neomycin for poultry, 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.

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

NEO-OXYVET

powder for oral solution

(55+55) mg/g

Oxytetracycline HCl + Neomycin sulfate

Pigs, Poultry (hens, turkeys)

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

1 g of product contains:

Active substances:

55mg Oxytetracycline hydrochloride (equivalent to 51mg Oxytetracycline base)

55mg Neomycin sulfate (equivalent to 38.5mg Neomycin base)

Excipient: Sucrose Powder

4. INDICATIONS

NEO-OXYVET powder for oral solution is recommended for:

Pigs: for the prevention and treatment of bacterial enteritis, dysentery, salmonellosis of piglets, as well as for the treatment of respiratory infections that are accompanied by gastrointestinal infections

Poultry: for the prevention and treatment of Chronic Respiratory Disease (C.R.D.), colibacillic septicemia, salmonellosis, infectious coryza, synovitis, hexamitiasis of turkeys, secondary infections that accompany infectious bronchitis and laryngotracheitis, non-specific enteritis and infectious bursal disease of turkeys

5. CONTRAINDICATIONS

Do not administer to laying hens producing eggs for human consumption.

6. ADVERSE REACTIONS

Tetracyclines may cause yellowing of teeth if administered during period of ossification

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 (hens and turkeys)

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

Administered per os.

The general dosage of oxytetracycline and neomycin administered per os to pigs and poultry is 10-20mg/kg of b.w. according to the severity of the disease. For more accurate dosing, the amount of product diluted in the drinking water must be calculated according to the body weight of the pigs or poultry, taking into account the actual water consumption.

For instance, a dose of 10mg/ kg of b.w. is as follows:

Poultry-Pigs

2g NEO-OXYVET powder for oral solution per 1L of drinking water (equivalent to 100mg Oxytetracycline and 77mg Neomycin / L of drinking water)

Should the symptoms remain after administration of the product for 2-3 days, consult your veterinary surgeon.

9. ADVICE ON CORRECT ADMINISTRATION

During treatment with NEO-OXYVET powder for oral solution assure that the medicated water is the only available source of drinking water for the animals.

10. WITHDRAWAL PERIODS

Meat and offal's:

Pigs: 5 days

Broilers: 14 days

Turkeys: 14 days

Do not administer to laying hens and turkeys that producing eggs for human consumption

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C.

Store in a dry place. Protected from light.

Shelf-life after dilution and according to the directions: 24 hours

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

12. SPECIAL WARNINGS

In case of possible or known hypersensitivity to tetracyclines or aminoglycosides, direct contact or inhalation in veterinary medicine product should be avoided.

Special warnings for each target species

None

Special precautions for use in animals:

The tetracyclines may cause yellowing of teeth if administered during the period of ossification

Special precautions to be taken by the person administering the veterinary medicinal product to animals

It is recommended to wear gloves and face masks. Wash hands after use.

Pregnancy and lactation

Not available

Interaction with other medicinal products and other forms of interaction

Generally, tetracyclines exhibit incompatibility with penicillins, cephalosporins, tylosin, chloramphenicol and hydrocortisone

Overdose (symptoms, emergency procedures, antidotes)

None reported

Incompatibilities

None known

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTEMATERIALS, 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
MARCH 2022

15. OTHER INFORMATION

PACKAGES

Alufoil sachet of 100 g

Can of 500 g and 1000 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