

PACKAGE LEAFLET

For animal treatment only

NEO-OXYVET

medicated premix 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

medicated premix

(44+44) g/kg

Oxytetracycline HCl + Neomycin sulfate

Pigs, Poultry (hens , turkeys)

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

1 kg of premix contains:

Active substances: 44g Oxytetracycline Hydrochloride (equivalent to 40.8g Oxytetracycline base),

44g Neomycin sulfate (equivalent to 30.8g Neomycin base)

Excipient: Wheat flower

4. INDICATIONS

NEO-OXYVET® medicated premix 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 sinusitis of the turkey.

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, ROUTE 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 added to the feed must be calculated according to the body weight of the pigs or poultry, taking into account the actual consumption of feed.

For instance, a dose of 10mg/ kg of b.w. corresponds to 5kg NEO-OXYVET® premix per tonne of feed (equivalent to 220g oxytetracycline hydrochloride and 220g neomycin sulfate per tonne of feed). Should the symptoms remain after administration of the product for 2-3 days, consult your veterinary surgeon.

9. ADVICE ON CORRECT ADMINISTRATION

Calcium ratio greater than 1% in the feed reduces the effectiveness of oxytetracycline, due to the formation of chelic compounds with ions of calcium and magnesium.

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 incorporation in the food according to directions: 3 months.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. 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

The use of tetracyclines during the periods of the last days of pregnancy and during period of tooth development, may lead to tooth discoloration.

Special precautions for use in animals:

None

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

People with potential or known hypersensitivity to tetracyclines or aminoglycosides should avoid direct contact or inhalation of the veterinary medicinal product.

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 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

MARCH 2022

15. OTHER INFORMATION

PACKAGES

Sack of 25 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