

PACKAGE LEAFLET

For animal treatment only

OXYVET® premix 10%

Medicated premix of oxytetracycline for chicken, pigs and mink

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

OXYVET® premix 10%

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

100 g of premix contain:

Active substance: 10 g Oxytetracycline HCl

Excipient: Wheat flour

4. INDICATION(S)

Oxytetracycline is a broad spectrum antibiotic. It is effective against Gram positive and negative microorganisms, certain mycoplasma, chlamydiae, rickettsiae and protozoa. Specifically, OXYVET® premix 10% is recommended for:

Chicken: for the prevention and treatment of mycoplasmosis (Chronic Respiratory Disease), colibacillosis, septicemia, cholera, typhoid, infectious coryza, synovitis, bursitis, hexamitiasis, secondary infections that accompany infectious bronchitis and laryngotracheitis.

Pigs: is recommended for the prevention and treatment of respiratory diseases, such as atrophic rhinitis, pulmonary pasteurellosis, mycoplasmal pneumonia (enzootic pneumonia), pleuropneumonia (due to *Haemophilus* spp.) and bronchopneumonia of piglets (due to *Bordetella bronchiseptica*). It is also recommended for the prevention and treatment of infections of the digestive system, such as bacterial enteritis, colibacillosis and salmonellosis of piglets.

Mink: for the treatment of systematic and topical infections such as bacterial diarrhea etc.

5. CONTRAINDICATIONS

Do not administer to animals with hepatic and renal failure.

Do not administer to laying hens.

6. ADVERSE REACTIONS

Tetracyclines tend to form complex with calcium ions (less so for doxycycline) and they are deposited - irreversibly - in the growing bones and unerupted teeth of young animals, or even the fetus. Drug bound by this way is pharmacologically inactive.

The use of tetracyclines in animals during the periods of late pregnancy and tooth development, may lead to tooth discoloration.

The intestinal flora may be affected, if treatment is extended for a long time and this may lead to gastrointestinal disorders.

If you notice any serious effects or other effects not mentioned in this package, please inform your veterinary surgeon.

7. TARGET SPECIES

Chicken, Pigs, Mink

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

OXYVET® premix 10% is administered per os mixed with feed, in the dosage per day given below:

Chicken, Pigs, Mink: 30 mg oxytetracycline/ kg bw or 0.3 g of the product per kg bw for 14 days.

9. ADVICE ON CORRECT ADMINISTRATION

Do not use in case of known hypersensitivity to tetracyclines.

The use of tetracyclines in animals during the periods of late pregnancy and tooth development, may lead to tooth discoloration.

Do not use in laying hens.

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

People with possible or known hypersensitivity to tetracyclines, should avoid inhalation or contact with the veterinary pharmaceutical product. It is recommended to use gloves and face masks. Wash hands after use.

10. WITHDRAWAL PERIOD

Chicken: Meat & offal: 7 days

Do not use in hens producing eggs for human consumption.

Pigs: Meat & offal: 7 days

11. SPECIAL STORAGE PRECAUTIONS

Store at temperatures below 25°C.

Shelf life after incorporation in the feed: 30 days

12. SPECIAL WARNING(S)

Tetracyclines should not be used in combination with bactericidal antibiotics. Should not be administered via milk substitutes. The absorption of tetracyclines from the GI tract is decreased by milk and milk products, antacids, kaolin, and iron preparations.

In monogastrics may be reduced the synthesis and availability of the B vitamins and vitamin K from the large intestine. With prolonged therapy, vitamin supplementation is a useful precaution.

Calcium ratio greater than 1% in the feed reduces the effectiveness of oxytetracycline.

Do not mix with other medicinal products. Generally, tetracyclines exhibit incompatibility with penicillins, cephalosporins, tylosin, chloramphenicol and hydrocortisone.

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

APRIL 2013

15. OTHER INFORMATION

PACKAGES

Sack of 5 kg and 25 kg

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 REACH AND SIGHT OF CHILDREN