

PACKAGE LEAFLET

For animal treatment only

OXYVET powder for oral solution 20%, for Pigs, Poultry, Dogs, Cats, Mink

1.NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION 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

Powder for oral solution,

20%, Oxytetracycline

for Pigs, Poultry, Dogs, Cats, Mink

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

100 g of product contain:

Active substance: 20 g Oxytetracycline Hydrochloride

Excipient: Lactose

4. INDICATIONS

OXYVET 20% powder for oral solution is recommended for the treatment of systematic and topical infections. Specifically:

Pigs: for bacterial respiratory diseases (such as bronchopneumonia and pleuropneumonia), for infections of the digestive system (such as bacterial enteritis, colibacillosis, salmonellosis), in cases of septicemic cases, erysipelas and also for infections of the urinary and genital system (such as pyelonephritis, endometritis, mastitis, prostatitis, etc.).

Poultry: for bacterial respiratory diseases, such as secondary infections that accompany infectious bronchitis and laryngotracheitis, in cases of colibacillosis, septicemia, cholera, typhoid, infectious coryza, bursitis, Chronic Respiratory Disease (C.R.D.), etc.

Dog-Cat: for infections of the respiratory, digestive, urinary and genital system, such as pyelonephritis, endometritis, mastitis, prostatitis, etc.

Also, it gives good results in the treatment of chlamydiosis, anaplasmosis, rickettsioses and nocardiosis.

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 mix in the feed, because it is water soluble powder.

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.

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, Dog, Cat, Mink

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

OXYVET 20% powder for oral solution is administered per os via the drinking water at the following daily dosage rates:

Pigs: 30 mg oxytetracycline/ kg of b.w. or 7.5 g of product per 50 kg of b.w. for 5 days

Poultry: 30 mg oxytetracycline/ kg of b.w. or 0.15 g of product per kg of b.w. for 5 days

Dogs-Cats-Mink: 54 mg oxytetracycline/ kg of b.w. or 0.27 g of product per kg of b.w. for 5 days

Daily dose should be split in two administrations. When administered, assure that the medicated water is the only source of drinking water.

9. ADVICE ON CORRECT ADMINISTRATION

Do not use in case of known hypersensitivity to tetracyclines.

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

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 PERIODS

Pigs: Meat & offal: 4 days

Poultry: Meat & offal: 7 days

Poultry: Eggs: 6 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 sachet/container. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

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, 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.

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

Sachet of 50 g

Metallic box of 500 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