PACKAGE LEAFLET

For animal treatment only

OXYVET 5 %

injectable solution of oxytetracycline for Sheep, Goats, Dogs, Cats

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
injectable solution, 5%
Oxytetracycline
for Sheep, Goats, Dogs, Cats

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

1 ml of solution contains:
Active substance: 50 mg Oxytetracycline Hydrochloride
Excipients: Sodium formaldehyde sulfoxylate, Magnesium chloride hexahydrate, Monoethanolamine, Water for injections, Propylene glycol

4. INDICATIONS

Oxytetracycline is a broad-spectrum antibiotic. It is active against positive and negative Gram microorganisms, certain mycoplasma, chlamydiae, rickettsiae and protozoa.
Oxytetracycline is indicated generally for infections of the digestive, respiratory and urogenital system, as well as septicemia of unknown reasons where a broad antimicrobial spectrum is needed.
In particular, **OXYVET** injectable solution 5% is recommended for the following cases:
Sheep-Goats: puerperal septicemia, gangrenous mastitis, puerperal infections, pneumonia
Dog-Cat: respiratory, urogenital and digestive infections, as well as septicaemia.

5. CONTRAINDICATIONS

Do not administer to animals with hepatic and renal failure.
Do not administer intravenously to dogs and cats.

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. A painful edema may form at the injection site, which resolves quickly.

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
Sheep, Goats, Dog, Cat

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
OXYVET injectable solution 5% is administered by deep intramuscular injection.
Oxytetracycline general dose for all approved target species is 5-10 mg/ kg of b.w., that is 1-2 ml OXYVET injectable solution 5% per 10 kg of b.w. for 3-5 days.

9. ADVICE ON CORRECT ADMINISTRATION
Do not administer at the same injection site amount exceeding 6 ml in sheep and goats
Do not administer 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
In case of potential or known hypersensitivity to tetracyclines, avoid direct skin contact or inhalation of vapors. It is recommended to wear gloves and face masks. Wash hands after use.

10. WITHDRAWAL PERIOD(S)
Meat & offal's:
Sheep: 11 days
Goats: 17 days
Milk: Do not use in animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS
Keep out of the sight and reach of children.
Store at temperatures below 25 ºC.
Shelf life after first opening of the immediate packaging: 28 days
Do not use this veterinary medicinal product after the expiry date which is stated on the label/box. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS
Tetracyclines should not be used in combination with bactericidal antibiotics.
Tetracyclines are joined and precipitate as insoluble yellow salts in tissues that are found in osteosis, such as bones and tooth, and this results in tooth discoloration.
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
MAY 2013

15. OTHER INFORMATION
PACKAGES
Vial of 50 ml and 100 ml
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