The following text is currently approved by the National Organization for Medicines (E.O.F.) in Greece and is subject to changes at any time.

PACKAGE LEAFLET

For animal treatment only

OXYVET 20% L.A.

injectable solution of oxytetracycline for sheep, goats and 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 & Ag.Anargyron, Thesi Vrago,
193 00 Aspropyrgos, Attiki, Greece

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

OXYVET 20% L.A.
injectable solution 20%
oxytetracycline
for sheep, goats, pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 ml of solution contains:
Active substance: 200 mg Oxytetracycline base (as Oxytetracycline dihydrate)
Excipients: 2-Pyrrolidone, Povidone, Magnesium oxide, Sodium formaldehyde sulfoxylate, Monoethanolamine, Water for injections

4. INDICATIONS

OXYVET 20% L.A. injectable solution is indicated for the control and treatment of diseases caused by pathogenic microorganisms sensitive to the action of oxytetracycline, such as against positive and negative Gram microorganisms, certain mycoplasma, chlamydiae, rickettsiae and protozoa.
OXYVET 20% L.A. injectable solution 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, the indications for each target species are as follows:
Sheep-Goats: pneumonia, metritis, infectious foot rot and polyarthritis, omphalitis of newborn, enzootic abortion and post-surgery or puerperal infections.
Pigs: pneumonia, erysipelas, arthritis, pasteurellosis, metritis-mastitis-agalactia syndrome (M.M.A.) and post-surgery or puerperal infections.
Preventively for the treatment of atrophic rhinitis (reduction of the severity of the disease).

5. CONTRAINDICATIONS

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

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.
When administered intramuscularly, 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, Pigs

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

OXYVET 20% L.A. is an injectable solution of tetracyclines for intramuscular use which because of its special composition it presents long acting.
It is administered undissolved by deep intramuscular injection.
Oxytetracycline dihydrate general dose for all target species is 20 mg/ kg of b.w., that is 1 ml OXYVET 20% L.A. injectable solution per 10 kg of b.w. at a single dose.

9. ADVICE ON CORRECT ADMINISTRATION

Special precautions for use in animals
Do not use in case of known hypersensitivity to tetracyclines.
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 contact or inhalation. It is recommended to wear gloves and face masks. Wash hands after use.

10. WITHDRAWAL PERIODS

Sheep: Meat & offal's: 16 days
Milk: 132 hours, (5.5 days, 11 milkings)
Goats: Meat & offal's: 24 days
Milk: 204 hours, (8.5 days, 17 milkings)
Pigs: Meat & offal's: 21 days

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

Special warnings for each target species:
During intramuscular injection, do not administer at the same injection site amount exceeding 5 ml in sheep and goats and 10 ml in pigs.

Pregnancy and lactation:

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

Interaction with other medicinal products and other form of interaction:
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.

Overdose (symptoms, emergency procedures, antidotes):
The provocation of poisoning by oxytetracycline is very rare, according to data mentioned in international bibliography (very few cases have been mentioned). In these incidents the direct interruption of administration of the medicinal product and the initiation of symptomatic treatment are imposed.

Incompatibilities:
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

JUNE 2017

15. OTHER INFORMATION

PACKAGES
Vials 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