

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

intrauterine pessaries of oxytetracycline for Mares, Cows, Ewes, Goats and Sows

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

intrauterine pessaries

Oxytetracycline

500ng/pessary

Mares, Cows, Ewes, Goats, Sows

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each pessary contains:

Active substance: Oxytetracycline Hydrochloride 500 mg

Excipients: Lactose, Maize starch, Povidone, Magnesium stearate, Microcrystalline cellulose, Alcohol

4. INDICATIONS

OXYVET pessaries are indicated solely after the period after parturition, for the treatment of endometritis and for puerperal infections of the uterus, as well as for cases in which the possibility of occurrence is seriously probable, provided that the relevant risk factors are present.

5. CONTRAINDICATIONS

None known

6. ADVERSE REACTIONS

None known

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

Mares, Cows, Ewes, Goats and Sows

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

The pessaries are placed deep in the uterine cavity.

Therapeutic administration:

Mares-Cows: 3-4 pessaries per animal

Ewes-Goats and Sows: 1-2 pessaries per animal

Administration when the risk factors are present:

Mares-Cows: 2-3 pessaries per animal given once

Ewes-Goats and Sows: 1 pessary per animal given once

9. ADVICE ON CORRECT ADMINISTRATION

In cases of presentation of clinical symptoms, the therapeutic administration can be repeated after 24 hours. In case of septicemia or generalized infection, at the time of placement of the pessaries in the uterus, general antibiotics must also be administered from the mouth or parenterally.

10. WITHDRAWAL PERIODS

Meat and edible tissues: 28 days

Milk: Cows, Ewes and goats: 48 hours.

Do not administer to mares, whose milk is intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 25°C

Do not use this veterinary medicinal product after the expiry date which is stated on container. Do not use this veterinary medicinal product after the expiry date which is stated on the box. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special warnings for each target species:

None

Special precautions for use in animals:

None required

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

In case of known hypersensitivity to tetracyclines, avoid direct skin contact with the product.

Wash hands after use.

Lactation, Pregnancy:

This product is for use only for the period after parturition.

Interaction with other medicinal products and other forms of interaction:

Tetracyclines bind and precipitate as non-soluble yellow salts onto tissues that are in process of ossification, namely bones and teeth, resulting in their discoloration.

Overdose (symptoms, emergency procedures, antidotes):

No data available.

Incompatibilities:

Tetracyclines should not be administered simultaneously 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 2021

15. OTHER INFORMATION

PACKAGES

Box of 10 and 20 pessaries in blister

Not all packages 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