

PACKAGE LEAFLET

FOR ANIMAL TREATMENT ONLY

OXYVET spray, aerosol for topical use on Sheep, Dog, Cat

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 spray

Aerosol for topical use

Oxytetracycline 3,5g/150g

Sheep, Dog, Cat

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each container of 150 g contains:

Active substance: 3.5 g Oxytetracycline Hydrochloride

Excipients: Aerosol OT, Isopropyl myristate, Polysorbate 80, Patent blue V, Isopropyl alcohol, Propane, Butane

4. INDICATIONS

OXYVET spray is recommended for external topical use for the prevention and treatment of infections of the skin, foot (foot rot), teats, lips and other general superficial skin infections caused by microbes susceptible to the drug. It is also recommended to use it as part of supportive treatment of skin burns, post-surgery infections and excoriations.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to tetracyclines.

6. ADVERSE REACTIONS

None

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, Dog, Cat

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

OXYVET spray is recommended only for topical application. Shake well before use.

Spray affected areas once or twice daily until complete healing. In severe cases, such as pododermatitis, treatment is applied after relative cleaning.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

10. WITHDRAWAL PERIOD

Sheep:

Meat and offal : Zero days

Milk: Zero days

11. PECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C. Protect from direct sunlight.

Pressurized container.

Protected from sun rays and temperatures above 50°C.

Do not pierce or incinerate even after use.

Do not spray on a naked flame or any incandescent material.

Flammable.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special precautions for use in animals:

Do not spray near the eyes. In case there is no improvement, discontinue the use of OXYVET spray and reconsider the diagnosis.

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

In case of probable or known hypersensitivity to tetracyclines, direct skin contact with or inhalation of the product (vapors) should be avoided. Wearing gloves and face mask is recommended during handling of the product. Wash hands after use.

Pregnancy and lactation: Not applicable.

Interaction with other medicinal products and other forms of interaction: None known

Overdose (symptoms, emergency procedures, antidotes): None known

Incompatibilities: None known

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

OCTOBER 2021

15. OTHER INFORMATION

PACKAGE:

Aluminum canister of 150 g

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

under veterinary medical prescription

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN