PACKAGE LEAFLET

For animal treatment only

OXYVET clear spray

Aerosol for topical use of oxytetracycline for sheep, goats, 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 CLEAR spray

Aerosol spray for topical use 2.2 g/container Oxytetracycline for sheep, goats, dog, cat

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

Each container of 95 g contains:

Active substance: 2.2 g Oxytetracycline Hydrochloride

Excipients: Sodium docusate, Isopropyl myristate, Polysorbate 80, Isopropyl alcohol

Propellant gases: Propane, Butane

4.INDICATIONS

OXYVET clear spray is recommended for external topical use for the prevention and treatment of infections of the skin, foot (foot rot), teats, lips and generally for all topical superficial skin infections caused by microbes susceptible to oxytetracycline. It is also recommended for the treatment of skin burns, post-surgery infections and excoriations.

5. CONTRAINDICATIONS

Do not use in case of known hypersensitivity to tetracyclines.

6. ADVERSE REACTIONS

None reported

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 AND METHOD OF ADMINISTRATION

OXYVET CLEAR spray is recommended only for topical application.

Spray affected areas once or twice daily until complete healing.

9. ADVICE ON CORRECT ADMINISTRATION

In severe cases, such as foot rot, treatment is applied after surgical debridement.

10. WITHDRAWAL PERIOD(S)

Sheep-Goats:

Meat & offal: 0 days

Milk: 0 days

Dog-Cat: Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C. Pressurized container.

Do not expose at sunlight and at temperatures above 50°C.

Do not pierce or incinerate the container even after use.

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

Keep away from children, food and feed.

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

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

12. SPECIAL WARNINGS

Special precautions for use in animals:

Do not spray around the eyes. In case sick animals do not correspond to the treatment with OXYVET CLEAR spray, interrupt its use and reevaluate diagnosis.

Where possible, use after sensitivity testing.

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 and keep the product away from the eyes. Its use should take place in well ventilated areas. Wash hands after use. Do not smoke whilst using the product. Do not spray on a naked flame or any incandescent material.

Pregnancy, lactation:

No data available.

Interaction with other medicinal products and other forms of interaction:

None known

Overdose (symptoms, emergency procedures, antidotes):

No data available.

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

DECEMBER 2015

15. OTHER INFORMATION

PACKAGES

Aluminum canister of 95 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