TOXYMAC SPRAY
(Oxytetracycline HCl)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

TOXYMAC SPRAY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of Spray Contains:
Oxytetracycline HCl ……. 35.8mg (3.58% w/w)

3. PHARMACEUTICAL FORM

Solution Spray

4. CLINICAL INFORMATION

4.1. Target species

Cattle & Sheep.

4.2. Indications for use specifying the target species

The veterinary medicinal product is indicated for topical use in the treatment of foot rot in sheep and topical infections caused by organisms sensitive to Oxytetracycline in cattle, sheep

4.3. Contraindications

Do not use in cases of known hypersensitivity to the active substance or to any of the other constituents.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

Special precautions for safe use in the target species:

For external use only.

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

Keep away from eyes.
Use only in a well-ventilated area.
Avoid inhalation and contact with skin.
Wash hands after use.

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

4.6. Adverse reactions (frequency and seriousness)

None known.
Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorization holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

4.7. Use during pregnancy and lactation or lay

Pregnancy and lactation:

No adverse effects or fatal abnormalities have been observed following the administration of Oxytetracycline aerosol during pregnancy and lactation.

4.8. Interaction with other veterinary medicinal products and other forms of interaction

None known

4.9. Dosage and administration route

Foot Rot
For the treatment of foot rot, clean the affected area prior to administration. Holding the can upright, spray at a distance of 6 - 8 inches away for a minimum of 5 seconds or until the area is covered.
Treated sheep should be allowed to stand on dry ground for one hour before returning to pasture.
Wounds:
Wounds should be cleaned prior to application.

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary

Not applicable.

4.11. Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

4.11. Withdrawal period:

Meat and offal: Zero days
Milk: Zero hours

5. PHARMACOLOGICAL PROPERTIES

ATC-vet code: **QD06AA03**.

5.1. Pharmacodynamics properties

Oxytetracycline is a bacteriostatic antibiotic that inhibits protein synthesis in susceptible bacteria. Inside the cell it binds irreversibly to receptors on the 30S subunit of the bacterial ribosome where it interferes with the binding of the aminoacyl-transfer RNA to the acceptor site on the messenger RNA ribosome complex. This effectively prevents the addition of amino acids to the elongating peptide chain, inhibiting protein synthesis.

5.2 Pharmacokinetic information

Oxytetracycline HCl in veterinary use shows moderate oral absorption, but bioavailability can be variable due to chelation with feed minerals. After parenteral administration, it is rapidly absorbed and widely distributed in body tissues, including lungs, kidneys, and liver, with moderate protein binding. The drug crosses the placenta and is excreted in milk. It undergoes minimal metabolism and is mainly eliminated unchanged via renal and biliary routes. The half-life ranges from about 6 to 10 hours depending on the species, dose, and route, making it suitable for both systemic and local (aerosol/spray) applications in animals.

6. PHARMACEUTICAL INFORMATION

6.1 Excipients:

Patent Blue V (E131) 0.3 % w/v
Magnesium Chloride
Povidone
Propylene Glycol
Ethanolamine
Purified Water
Isopropyl Alcohol
Methyl Alcohol

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the container: use immediately in 28 days, do not store.

6.4. Special precautions for storage

Store below 25°C.
Protect from light and moisture.
Pressurized container, do not expose to temperatures above 50°C.
Shake well before use
Keep out of the reach of children.
To be used as directed by the registered veterinary practitioner only.

6.5. Nature and composition of primary conditioning

Sealed aerosol spray can with nozzle.
Pack sizes: 150ml & 300ml

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF WASTE MATERIALS
UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS

Waste materials derived from the use of such products
Medicinal products should not be disposed of via wastewater or household waste.
Use return systems for unused veterinary medicinal products or waste materials derived from such products, in accordance with local requirements and national collection systems applicable to the veterinary medicinal product concerned.
Treated animals should be kept in shelters throughout the treatment period and their droppings should be collected and NOT used for soil fertilization.

7. MARKETING AUTHORISATION HOLDER

Nawan Laboratories (Pvt.) Ltd.
Plots No. 136-138, Sector-15,
Korangi Industrial Area, Karachi-74900, Pakistan.

8. MARKETING AUTHORISATION NUMBER

Reg. No.: 082486

9. DATE OF FIRST AUTHORISATION

Date of Reg: 22-09-2017

10. DATE OF REVISION OF THE TEXT

17-02-2025

MANUFACTURED BY:

NAWAN LABORATORIES (PVT) LTD.
136, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan.