

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphacycline Aerosol

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 140g aerosol can contains:

Active Substance

Oxytetracycline 3.2 % w/v
(as oxytetracycline hydrochloride)

Excipient

Patent Blue V (E131) 0.3 % w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray, solution.

A blue opaque solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep

4.2 Indications for use, specifying the target species

Duphacycline Aerosol is indicated for the treatment of foot rot and topical infections caused by organisms sensitive to oxytetracycline in sheep.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active substance.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precaution(s) for use in animals

None

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

Keep away from eyes.
Avoid contact with skin.
Avoid inhaling vapours.
Wash hands after use.
Do not spray on a naked flame or any incandescent material.
Highly flammable.
Must be used in a well-ventilated area.
Do not smoke when using this product.

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

The product can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None

4.9 Amounts to be administered and administration route

Before spraying the infected area, the hooves should be cleaned and pared. Shake the can before use. Spray at a distance of 6-8 inches away for at least 5 seconds.

Treated sheep should be allowed to stand on dry ground for one hour before returning to pasture.

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

Not applicable.

4.11 Withdrawal Period(s)

Meat and offal: Zero days
Milk: Zero hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibiotics for topical use, oxytetracycline.
ATCvet code: QD06AA03

5.1 Pharmacodynamic 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Patent Blue V (E131)
Magnesium chloride
Povidone
Propylene Glycol
Ethanolamine
Water for Injections
Isopropyl Alcohol
Methyl Alcohol

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Do not store above 25°C.

Pressurised container, protect from sunlight and do not expose to temperatures above 50°C. Do not pierce or burn, even when empty.

6.5 Nature and composition of immediate packaging

Aluminium monobloc cans with valves caps and actuators.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Do not incinerate or puncture the can even when empty.

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Zoetis Ireland Limited
25/28 North Wall Quay
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/028/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT

August 2013