

Part II
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tectin Aerosol Cutaneous spray solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 140g aerosol contains 5g Oxytetracycline Hydrochloride 3.6% w/w and Patent blue V (E131) 0.33% w/w as colorant.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cutaneous spray solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep and pigs.

4.2 Indications for use, specifying the target species

Indicated for the treatment of foot rot and topical infections caused by organisms sensitive to oxytetracycline in cattle, sheep and pigs.

4.3 Contra-indications

None

4.4 Special warnings for each target species

None

4.5 Special precautions for use

(i) Special precautions for use in animals

For external use only.

(ii) 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 or lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None

4.9 Amounts to be administered and administration route

For the treatment of foot rot, the hooves should be cleaned and pared prior to administration. Wounds should be cleaned prior to administration. Shake the can before use. Spray for a few seconds or until the lesion is adequately covered.

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 – Zero days

Milk - Zero days

5. PHARMACOLOGICAL PROPERTIES

Oxytetracycline is a bacteriostic 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 amino-acyl transfer RNA to the acceptor site on the messenger RNA Ribosome complex. This effectively prevents the addition of the amino acids to the elongating peptide chain, inhibiting protein synthesis.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium chloride hexahydrate

Povidone

Patent Blue V (E131)

Propylene glycol

Purified water

Ethanolamine

Isopropyl 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

Pressurised container, protect from sunlight and do not expose to temperatures above 50°C.
Do not pierce or burn, even after use.
Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Aluminium monobloc cans with valves caps and actuators (140g pack size).

The propellant is Nitrogen (oxygen-free).

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Vétoquinol UK Limited
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8. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4033

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09 March 1992/09 March 2007

10. DATE OF REVISION OF THE TEXT

November 2007