Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Orospray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100g powder contains :		
Active substances:		
Chlortetracycline (as hydrochloride)	2.850	g
Sulfanilamide	50.000	g
Excipients:		
Methyl parahydroxybenzoate	0.115	g

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray, powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses, Cattle, Goat, Sheep and Dog.

4.2 Indications for use, specifying the target species

For the topical treatment of wounds infected by organisms sensitive to the active ingredients.
For the prevention and treatment of post operative infections following surgical procedures by topical application.

4.3 Contraindications

Do not use in animals with known hypersensitivity to one of the ingredients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

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

Pressurised container.
Do not spray on or near a naked flame or any incandescent material.
Do not smoke.
Do not use or store near an open flame, heat, ignition and sparkle source, electric device in use. The product should be used unaltered from the original container.
Treat animals outdoors or in a well ventilated area.
Shake well before use.
Do not apply to the mammary gland when milk is for human consumption.
In case of obstruction of the spray nozzle, turn the container up side down and press the valve.
Proceed with short pressures without prolonged spraying.

4.6 Adverse reactions (frequency and seriousness)

Possible cutaneous reaction due to sulfanilamide in horses.

4.7 Use during pregnancy, lactation or lay

The product may be used in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Lesions should be treated 2 to 3 times daily depending on their severity.

Administration is by topical application only.

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

None known.

4.11 Withdrawal Period(s)

Meat and offal: 15 days

Milk: 5 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibiotics for topical use; chlortetracycline, combinations.
ATCvet Code: QD06AA52

5.1 Pharmacodynamic properties

Tetracyclines have a broad spectrum of antimicrobial activity including Chlamydias, Mycoplasma, Rickettsia and Spirochaetes, and also many aerobic and anaerobic gram-positive and gram-negative pathogenic bacteria and some protozoa.

Chlortetracycline is somewhat less active against many gram negative organisms.

Mechanism of action of Tetracycline: they are taken up into sensitive bacterial cells by an active transport process. Once within the cells they bind reversibly to the 30S subunit of the ribosome, preventing the binding of aminoacyl transfer RNA and inhibiting protein synthesis and hence cell growth. Although tetracyclines inhibit protein synthesis in mammalian cells they are not actively taken up, permitting selective effects on the infecting organism.

Sulphonamides have a similar structure to p-amino-benzoic acid and interfere with the synthesis of nucleicacids in sensitive micro-organisms by blocking the conversion of p-amino-benzoic acid to coenzyme dihydrofolic acid, a reduced form of folic acid; in man,
dihydrofolic acid is obtained from dietary folic acid so sulphonamides do not affect human cells.

The following strains may demonstrate sensitivity to them: gram positive cocci, gram positive bacteria, gram negative cocci (but some of them are now resistant), gram negative bacteria.

Actions of Tetracyclines and Sulphonamides are essentially bacteriostatic.

5.2 Pharmacokinetic properties

Chloretetracyline is reported to be rapidly inactivated in the body with a half-life of about 6 hours and is largely eliminated by biliary excretion. About 45% of the dose is protein bound.

Transmembranal absorption is conditioned by liposolubility of Sulfonamide and by its degree of ionization, according to the rules of passive diffusion. pKa of Sulfonamide is 10.4. This molecule presents a good tissular diffusion. This substance exists predominantly under ionized form in biologic fluids. Protein binding of Sulfanilamide is weak (<20%). Its diffusion in tissue is therefore important. Its half-life is low: about 6 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate
Monoacetyl urea
Sesame Oil
Sorbiton Trioleate
Liquid petroleum

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Protect from direct sunlight.
The product should be stored below 30^0C.
To avoid a risk of explosion, do not expose to temperature above 50^0C.

6.5 Nature and composition of immediate packaging

A cutaneous spray powder supplied in an aluminium pressurised container of 210 ml size.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited
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19/20 Earlsfort Terrace
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10983/008/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th October 1988
Date of last renewal: 30th September 2008

10 DATE OF REVISION OF THE TEXT

August 2015