Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Spimetryl 55 mg/g Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains :

Active substance

Chlortetracycline Hydrochloride	5.5 % w/w

Excipients

Lissamine green (E142)	0.058% w/w

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.
A green soluble powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Calves

4.2 Indications for use, specifying the target species

For the treatment of respiratory, enteric and systemic infections associated with chlortetracycline-sensitive organisms.

4.3 Contraindications

Do not use in animals with functional rumens.
Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use

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.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to chlortetracycline and may decrease the effectiveness of treatment with tetracyclines, due to the potential for cross resistance.

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

None.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

This product is not indicated for use in pregnant or lactating cattle.

4.8 Interaction with other medicinal products and other forms of interaction

Avoid use of contaminated water and rusty or dirty containers.

4.9 Amounts to be administered and administration route

For oral administration as a soluble powder, to be given as a drench.

Therapeutic doses of chlortetracycline hydrochloride are for:
Calves: 10-20 mg/kg bodyweight daily

Treatment should be continued for a period of five to seven days.
The product may be given in a drench twice daily at the rate of 12.5 g (3 rounded 5 ml teaspoonfuls) per 45 kg bodyweight daily, split into 2 x 12-hourly doses in sufficient water to dissolve it (this is equivalent to 600 mg Chlortetracycline daily). Prepare drench immediately prior to administration.

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

Chlortetracycline is of low toxicity and there is a wide safety margin at the recommended dosage. On rare occasions overdosage may cause diarrhoea or over-growth of yeasts and fungi. Withdraw medication and apply appropriate treatment.

4.11 Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment. Animals may be slaughtered for human consumption only after the following number of days from the end of treatment:

Calves: 25 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, tetracyclines
ATCvet Code: QJ01AA03

5.1 Pharmacodynamic properties

Chlortetracycline is a broad spectrum antibiotic of the tetracycline group. When dosed orally it is absorbed into the blood stream, achieving effective concentrations in various tissues, including lungs and other respiratory tissues. It is excreted in urine and faeces. At recommended dosages it has no pharmacological effects on cardiovascular, nervous or other body systems.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid anhydrous
Lissamine green (E142)
Polysorbate 80
Lactose monohydrate

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal procudt as packaged for sale: 3 years.
Medicated solutions should be used within 24 hours. In hard water areas, medicated solutions must be used within 12 hours.

6.4 Special precautions for storage

Store in a dry place. Keep the container tightly closed.
Do not store above 25^0C.

6.5 Nature and composition of immediate packaging

Available in:

(a) 225g opaque grey polypropylene tabs sealed with an opaque white low density polyethylene lid (push fit)

(b) 5kg white polypropylene copolymer buckets (with 2x2.25 kg polyethylene bags inside) sealed with a green polypropylene copolymer lid (push fit).

Not all pack sizes may be marketed.

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

Pfizer Animal Health
Ringaskiddy
Co. Cork
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/125/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT

December 2010