Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

RESPICHLOR 15% w/w Oral Powder.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains

Active substance
Chlortetracycline hydrochloride 150 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral Powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Calves (less than 6 months of age).

4.2 Indications for use, specifying the target species

The product is indicated as an aid in the treatment of respiratory disease in calves caused by *Pasteurella spp*., sensitive to chlortetracycline.

4.3 Contraindications

Do not use in adult ruminants, dairy cows and veal calves.
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 in animals

Ideally, use of the product should be based on susceptibility testing.

Inappropriate use of the product may increase the prevalence of bacteria resistant to chlortetracycline and may decrease the effectiveness of treatment with related substances, due to the potential for cross-resistance.

To ensure the correct dosage and to avoid possible under-dosing, the bodyweight should be determined as accurately as possible

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

When incorporating into feed, care must be taken not to inhale any dust. It is recommended that a face mask be worn during the dispensing and mixing of the product.
Avoid skin contact when handling this product. Wash hands and all exposed skin at the end of the operation.

4.6 Adverse reactions (frequency and seriousness)

Chlortetracycline toxicity is low. If digestive disturbances do occur, treatment should be discontinued.
Long term use of this product is not recommended as it may lead to the development of bacterial resistance.

4.7 Use during pregnancy, lactation or lay

This product is not recommended for use in pregnant or lactating cows.

4.8 Interaction with other medicinal products and other forms of interaction

This product is not recommended for concurrent administration with any other oral medication.

4.9 Amounts to be administered and administration route

For oral administration.

The product should be administered as a top dressing to small quantities of feed for immediate consumption by individual animals.

The recommended therapeutic dose is 20 mg per kg bodyweight daily i.e. 20 grams of *RESPICHLOR 15% Oral Powder* per 150 kg bodyweight. This should be given in a divided daily dose i.e. 10 g morning and 10 g evening. Treatment should be continued for a period of seven days.

Calf Weight (kg)	**Dose (to be given twice daily)**	
	Weight in g	**Scoopful (5g size)**
Up to 75	5	1
150	10	2
225	15	3

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

Do not exceed the stated dose.
Chlortetracycline toxicity is low. If digestive disturbances do occur, treatment should be discontinued.
Long term use of this product is not recommended as it may lead to the development of bacterial resistance.

4.11 Withdrawal Period(s)

Meat**:** 35 days. Calves must not be slaughtered for human consumption during treatment.
Milk: Do not use in dairy cows

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlortetracycline hydrochloride is a bacteriostatic antibiotic, interfering with bacterial protein synthesis of the rapidly growing and reproducing bacterial cell.

5.2 Pharmacokinetic properties

Following oral absorption, maximum blood levels are achieved in approximately 2-8 hours. The CTC plasma concentration maintains a steady state level until day 7, following the consecutive twice-daily medications.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal anhydrous silica
Medium chain triglycerides
Soya bean meal

6.2 Incompatibilities

Incompatible with substances containing ionophores.

6.3 Shelf-life

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

6.4 Special precautions for storage

Store below 25^{o}C.
Protect from light.

6.5 Nature and composition of immediate packaging

1 kg in LDPE bags laminated with metallised polyester.

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

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

7 MARKETING AUTHORISATION HOLDER

Interchem (Ireland) Ltd.,
29 Cookstown Industrial Estate,
Dublin 24,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10555/004/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26th June 2006

10 DATE OF REVISION OF THE TEXT

January 2012.