1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Respichlor 150 mg/g oral powder for calves.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substances:
Chlortetracycline hydrochloride 150 mg

Excipients:

Qualitative composition of excipients and other constituents
Colloidal anhydrous silica
Medium chain triglycerides
Soya bean meal

A yellow uniform powder.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calves less than 6 months of age).

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use in adult ruminants, dairy cows and veal calves.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

Inappropriate use of the veterinary medicinal 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.

Long term use of this veterinary medicinal product is not recommended as it may lead to the development of bacterial resistance.

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. Personal protective equipment consisting of protective goggles, impervious gloves and a dust mask to BS EN 143:2000 should be worn when mixing the veterinary medicinal product to avoid direct contact with the skin and inhalation of the product.
Avoid skin contact when handling this veterinary medicinal product. Wash hands and all exposed skin at the end of the operation.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (calves less than 6 months of age):

Undetermined frequency (cannot be estimated from the available data):	Gastrointestinal disorder[1]

[1]Treatment should be discontinued.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the immediate packaging for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
This veterinary medicinal product is not recommended for use in pregnant or lactating cows.

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

Oral use.

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

The daily recommended dose is 20 mg chlortetracycline per kg bodyweight daily equivalent to 20 g of the veterinary medicinal product 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.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Do not exceed the stated dose.
Chlortetracycline toxicity is low. If digestive disturbances do occur, treatment should be discontinued.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Meat and offal: 35 days.
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QJO1AA03

4.2 Pharmacodynamics

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

4.3 Pharmacokinetics

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Incompatible with substances containing ionophores.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25 °C.
Protect from light.
Keep the container tightly closed after use.

5.4 Nature and composition of immediate packaging

1 kg in LDPE bags laminated with metallised polyester.
5 x 1 kg in LDPE bags laminated with metallised polyester in a cardboard carton.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Interchem (Ireland) Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10555/004/001

8. DATE OF FIRST AUTHORISATION

29/06/2001

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10/11/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).