SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chloromed 150 mg/g oral powder for pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:

Chlortetracycline hydrochloride 150 mg

Excipients:

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

A coarse, yellow powder.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated in the treatment of respiratory disease in pigs caused by micro- organisms sensitive to chlortetracycline.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals with severe liver and renal disorders.

3.4 Special warnings

The uptake of oral medication by animals can be altered as a consequence of illness.
In case of insufficient uptake of feed, animals should be treated parenterally.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The veterinary medicinal product is efficient only against bacterial strains most sensitive to chlortetracycline. Use of the veterinary medicinal 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.

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.

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:

Handle this veterinary medicinal product with care to avoid exposure when adding to feed and administering medicated feed to the animals. Take adequate measures to avoid dust formation when adding the veterinary medicinal product to feed.

Those handling the veterinary medicinal product should do so in a mechanically ventilated area.

Personal protective equipment consisting of protective gloves, overalls and approved safety glasses should be worn when handling the veterinary medicinal product. Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143.

Direct contact of the veterinary medicinal product with the skin, eyes and mucous membranes should be avoided. In case of accidental exposure, wash area immediately with water.

Do not smoke, eat or drink when handling the veterinary medicinal product.
Hands and exposed skin should be washed thoroughly after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs:

Rare (1 to 10 animals / 10 000 animals treated):	Allergic reactions, [1]
	Liver disorders,[1]
	Renal disorders,[1]
	Gastrointestinal disorders,[1]
	Photosensitivity.[1]

[1] If suspected adverse events occur, 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 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:

The use is not recommended during pregnancy or lactation. The treatment of pregnant animals with chlortetracycline may result in adverse effects on skeletal and tooth development in the foetus. Therefore, the veterinary medicinal product should be used only in pregnant sows according to the benefit-risk assessment of the responsible veterinarian.

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.
Do not add the veterinary medicinal product to feed overloaded with polyvalent cations such as Ca^{2+} and Fe^{3+} because the formation of chlortetracycline complexes with these cations is possible.
Do not administer together with antacids, kaolin and iron preparations and in conjunction with bactericidal antibiotics like beta-lactams.

3.9 Administration routes and dosage

Oral use.
The recommended therapeutic dose is 20 mg per kg bodyweight (equivalent to 20 g of the veterinary medicinal product per 150 kg bodyweight) per day administered for seven days. This should be given in a divided daily dose i.e. 10 g morning and 10 g evening. As a guide to dosing pigs of different weight, see table.

The veterinary medicinal product should be administered to small quantities of feed for immediate consumption by individual animals. Larger groups should be treated with medicated feeding stuff.

The veterinary medicinal product should be mixed thoroughly into a part of the daily feed ration and should be administered prior to the feeding. It should be ensured that the calculated dose is completely taken up by the animal.

If animals don’t recover within 3 days after oral medication, diagnosis should be reconsidered and treatment should be changed, if necessary.

To ensure a correct dosage bodyweight should be determined as accurately as possible. To determine the correct amount of veterinary medicinal product, a calibrated weighing scale should be used.

Dosing Table:

Pig Bodyweight (kg)	Daily amount (g) of Chloromed 150	Dose (g) – to be given TWICE daily
15 kg	2g	1g
30 kg	4g	2g
60 kg	8g	4g
75 kg	10g	5g
150 kg	20g	10g

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: 6 days.

4. <PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01AA03

4.2 Pharmacodynamics

Chlortetracycline hydrochloride is a predominantly bacteriostatic antibiotic, interfering with bacterial protein synthesis of the rapidly growing and reproducing bacterial cell.
Chlortetracycline has a broad spectrum of activity, including Gram-positive aerobes, Gram-negative anaerobes and Mycoplasmas. Resistance is known to occur in respiratory pathogens of pigs and cross-resistance occurs between chlortetracycline and other tetracyclines.

The Clinical and Laboratories Standards Institute (CLSI) breakpoints established for tetracyclines are as follows:
Organisms other than streptococci: S: ≤ 4µg/ml, I: 8 µg/ml; R: ≥ 16 µg/ml.

4.3 Pharmacokinetics

Following oral administration, maximum blood levels are achieved within approximately 2- 8 hours. Steady state plasma concentrations of chlortetracycline are maintained throughout the twice daily seven day treatment period.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store in a dry place.
Store in the original container.
Protect from light.

5.4 Nature and composition of immediate packaging

1 kg, clear low density polyethylene bag laminated with metallised polyester.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Univet Limited

7. MARKETING AUTHORISATION NUMBER

Vm 05150/4002

8. DATE OF FIRST AUTHORISATION

14 January 2011

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

May 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 12 June 2026