1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chloromed 150 mg/g premix for medicated feeding stuff for calves

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each g contains:

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

Calves (less than 6 months of age).

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use in calves over 6 months of age and dairy cows.
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:

Use of the veterinary medicinal product should be based on susceptibility testing and take into account official and local antimicrobial policies.

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 incorporating into feed and administering medicated feed to the animals.

Take adequate measures to avoid dust formation when incorporating the veterinary medicinal product into feed.

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

Wear either a disposable half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143.

Personal protective equipment consisting of gloves, overalls and approved safety glasses should be worn when handling the veterinary medicinal product.

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

Do not smoke, eat or drink when handling the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Calves (less than 6 months of age):

Rare (1 to 10 animals / 10 000 animals treated):	Allergic reaction; Liver disorder; Renal disorder; Gastrointestinal disorder[1]; Photosensitivity.

[1.] If digestive disturbances occur, treatment should be discontinued.

If suspected adverse reactions occur, treatment should be discontinued.
Due to the possible incorporation of chlortetracycline, treatment of pregnant and newborn animals can lead to dysfunctional development of the skeleton and teeth in foetal and growing animals.

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:

Not applicable.

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 incorporate the veterinary medicinal product in 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.
The veterinary medicinal product should not be used in cases of known resistance to other tetracyclines.

3.9 Administration routes and dosage

Oral use.

The recommended therapeutic dose is 20 mg per kg bodyweight daily i.e. 20 grams per 150 kg bodyweight.

For the preparation of the medicated feed the body weight of the animals to be treated and their actual intake of feed should be taken into account. To ensure a correct dosage, body weight should be determined as accurately as possible. The required dose should be measured by suitably calibrated weighing equipment. During the treatment period, only feed medicated with the veterinary medicinal product should be supplied. To provide the required amount of active substance per kg medicated feed, the premix has to be incorporated into the feed according to the following formula:

$$\frac{\dots \text{ mg veterinary medicinal product/kg bw/day x Average bw (kg) of animals to be treated}}{\text{Average daily feed intake (kg/ animal)}} = \cdots \text{ mg veterinary medicinal product / kg of feed}$$

Treatment should be continued for a period of seven days. If animals don't recover within 3 days after oral medication, diagnosis should be reconsidered and treatment should be changed, if necessary.

The uptake of medicated feed depends on the clinical condition of the animals. In order to achieve the correct dosage the chlortetracycline inclusion rate in feed should be adjusted for feed intake.

Pelleting should not be conducted at temperatures in excess of 70 °C.

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.
Milk: Not authorised for use in animals producing milk for human consumption.

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 cattle 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: $\leq$ 4µg/ml, I: 8 µg/ml; R: $\geq$ 16 µg/ml.

4.3 Pharmacokinetics

Following oral administration of the recommended dose, maximum blood levels of approximately 1 – 2 µg/ml are achieved within 2 – 8 hours and approximately 37% of the oral dose is systemically available. Steady state

plasma concentrations of chlortetracycline are maintained throughout the twice-daily seven day treatment period.
Chlortetracycline accumulates in the lung tissue resulting in higher concentrations at the site of activity.
Chlortetracycline undergoes little metabolism and is excreted through both the urinary and biliary systems.

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: 1 month.
Shelf life after incorporation into meal or pelleted feed: 4 weeks (if stored below 25 ˚C).

5.3 Special precautions for storage

Store below 25°C.
Store in a dry place.
Store in the original container.
Protect from light.

5.4 Nature and composition of immediate packaging

25 kg, white low density polyethylene bag in a triple layered paper bag.

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

Univet Ltd.

7 MARKETING AUTHORISATION NUMBER(S)

VPA10990/040/001

8 DATE OF FIRST AUTHORISATION

11/12/2009

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

14/05/2026

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).