SUMMARY OF PRODUCT CHARACTERISTICS

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 150 mg chlortetracycline hydrochloride.

Excipient(s):

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff.
A coarse, yellow powder.

4. CLINICAL PARTICULARS

4.1 Target species

Calves (less than 6 months of age).

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in calves over 6 months of age and dairy cows.
Do not use in animals with known hypersensitivity to tetracycline.
Do not use in animals with severe liver and renal disorders.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

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

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.

Long term use of this 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 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 product should do so in a mechanically ventilated area.

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.

Wear protective gloves, overalls and approved safety glasses.

Direct contact of the veterinary medicinal product with the skin, the eyes and the 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

Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

Chlortetracycline toxicity is low. If digestive disturbances do occur, treatment should be discontinued.
On rare occasions the following adverse reactions may occur: allergic reactions and photosensitivity; gastrointestinal disorders; disorders of the liver and the kidneys. 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.

4.7 Use during pregnancy, lactation or lay

Not applicable.

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.
Do not incorporate the 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 product should not be used in case of known resistance to other tetracyclines.

4.9 Amounts to be administered and administration route

For oral administration after incorporation in a feeding stuff by a facility licensed to medicate feed.

Administration:

The recommended therapeutic dose is 20 mg per kg bodyweight daily i.e. 20 grams of Chloromed 150 mg/g Premix 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 the correct dosage and to avoid under-dosing, the 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 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:

$$\frac{\text{... mg Chloromed/kg bw/day x Average bw (kg) of animals to be treated}}{\text{Average daily feed intake (kg/animal)}} = \text{... mg Chloromed/kg of feed}$$

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.

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.

4.11 Withdrawal periods

Calves
Meat and offal: 35 days.
Milk: The product is contraindicated for use in adult ruminants and dairy cows and should therefore not be used in animals producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Tetracycline for systemic use.
ATCvet code: QJ01AA03

5.1 Pharmacodynamic properties

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: ≤ 4µg/ml, I: 8 µg/ml; R: ≥ 16 µg/ml.

5.2 Pharmacokinetic particulars

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 bilary systems.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Medium Chain Triglycerides.
Soya Bean Meal.
Colloidal anhydrous silica.

6.2 Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening of the immediate packaging: 1 month
Shelf life after incorporation into meal or pelleted feed: 4 weeks (if stored below 25˚C)

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Univet Ltd
Tullyvin
Cootehill
Co. Cavan
Ireland

8. MARKETING AUTHORISATION NUMBER

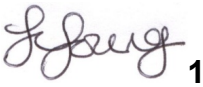
Vm 05150/4000

9. DATE OF FIRST AUTHORISATION

28 October 2009

10. DATE OF REVISION OF THE TEXT

September 2014

Approved:  **17/09/2014**