SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chloromed 150 mg/g Oral Powder 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

Oral Powder.
Yellow uniform powder / a yellow powder.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (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

People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.
Do not eat, drink or smoke while handling the product or medicated feed.
During preparation and administration of the medicated feed, skin contact with the product and inhalation of dust particles should be avoided.
Personal protective equipment consisting of protective overall, glasses, impermeable gloves (e.g. rubber or latex) and an appropriate dust mask (e.g. disposable half mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143) should be worn when handling the veterinary medicinal product.
Wash hands immediately after handling the product or medicated feed.
In the event of skin or eye contact, rinse immediately the affected area with large amounts of clean water. If irritation occurs, seek medical attention.
If you develop symptoms following exposure to the product such as skin rash, you should seek medical advice and show the present warning to the doctor. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

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.

The recommended therapeutic dose is 20 mg chlortetracycline per kg bodyweight (equivalent to 20 grams of Chloromed 150 mg/g Oral Powder 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.

The 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 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 animals.

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

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

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

Cattle (Calves):
Meat and offal: 10 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: Antibacterials for systemic use, tetracyclines

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.
Glucose Monohydrate.
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 the immediate packaging: 28 days

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

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

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 05150/4001

9. DATE OF FIRST AUTHORISATION

Date: 29 October 2009

10. DATE OF REVISION OF THE TEXT

Date: December 2014

Approved: 16 December 2014