Chloromed 150 mg/g Data Sheet

Oral Powder for Pigs

Chloromed is a coarse yellow powder, containing 150 mg/g chlortetracycline hydrochloride per g.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chloromed 150 mg/g Oral Powder for Pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each g contains 150 mg chlortetracycline hydrochloride.

Excipient(s):

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral Powder.

A coarse, yellow powder.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the target species

Pigs:

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

4.3 Contraindications

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

i Special precautions for use in animals

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

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

Handle this 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 product to feed.

Those 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.

Direct contact of the product with the skin, eyes and mucous membranes should be avoided.

Wear protective gloves, overalls and approved safety glasses.

In case of accidental exposure, wash area immediately with water.

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

Hands and exposed skin should be washed thoroughly after use.

iii. 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.

See Section 4.7

4.7 Use during pregnancy, lactation or lay

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 product should be used only in pregnant sows according to the benefit/risk assessment of the responsible veterinarian.

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 add the product to feed overloaded with polyvalent cations such as Ca2+ and Fe3+ 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 hydrochloride 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. As a guide to dosing pigs of different weight, see table.

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 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 the correct dosage and to avoid possible under-dosing, the bodyweight and the amount of product administered should be determined as accurately as possible. To determine the correct amount of 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

4.10Overdose (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.

4.11Withdrawal periods

Pigs:

Meat and offal: 6 days.

4.12PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Tetracycline for systemic use.

ATCvet code: QJ01AA03

5. 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 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.

5.1 Pharmacokinetic particulars

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.

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 the immediate packaging: 28 days

6.4 Special precautions for storage

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 product or waste materials should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Univet Ltd.

Tullyvin

Cootehill

Co. Cavan

Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 05150/4002

9. DATE OF FIRST AUTHORISATION

Date:14 January 2011

10. DATE OF REVISION OF THE TEXT

Date:January 2011