Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains

Active substance:

Chlortetracycline hydrochloride 150 mg

Excipients:

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

Pigs.

4.2 Indications for use, specifying the target species

Pigs:
The product is indicated in the treatment of the 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

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 the 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.

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 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 EN 149 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.

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 (more than 1 but less than 10 animals in 10,000 animals) 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.

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 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 hydrochloride 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 Period(s)

Pigs:
Meat and offal: 6 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL 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 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.

5.2 Pharmacokinetic properties

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

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

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

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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(S)

VPA 10990/043/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th February 2011
Date of last renewal: 4th February 2016

10 DATE OF REVISION OF THE TEXT

July 2016