1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chloromed 500 mg/g powder for oral solution for chickens and pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:
465 mg Chlortetracycline
(equivalent to 500 mg chlortetracycline hydrochloride)

Excipients:

Qualitative composition of excipients and other constituents
Citric acid

A yellow powder.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (broilers) and pigs.

3.2 Indications for use for each target species

For use in the treatment of infections due to susceptible bacteria in broiler chickens and pigs.

Chickens: The veterinary medicinal product is used in the treatment and metaphylaxis of colibacillosis secondary to infectious bursal disease, chronic respiratory disease caused by *Escherichia coli*, and *Pasteurella multocida* infections.

Pigs: The veterinary medicinal product is used in the treatment and metaphylaxis of respiratory diseases associated with *Mycoplasma hyopneumoniae*, *Steptococcus suis* and toxigenic strains of *Pasteurella multocida*. It is also used in the treatment and metaphylaxis of rhinitis due to *Bordetella bronchiseptica* and streptococcal meningitis due to *Streptococcus suis* type II.

The presence of the disease in the group or flock must be established before the product is used.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to the excipient.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Chlortetracycline must be used cautiously in patients with renal insufficiency or hepatic impairment.

Use of the product should be based on identification and susceptibility testing of the target pathogens. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

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.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

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

Chlortetracycline may cause hypersensitivity reactions.
People with known hypersensitivity to tetracyclines should avoid skin contact and inhalation of dust particles during preparation and administration of the medicated drinking water.
Do not eat, drink or smoke while handling the product or medicated drinking water. 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 drinking water. In the event of skin or eye contact, rinse immediately the affected area with large amounts of clean water. Seek medical attention if irritation occurs/persists. If you develop symptoms following exposure to the product such as skin rash, you should seek medical advice and show the label or package leaflet to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:

The veterinary medicinal product may be toxic to plants. In order to prevent any adverse effects on terrestrial plants, manure must not be spread onto land without dilution with manure from untreated animals. Manure should be diluted with at least the same weight of manure from untreated animals.
After dilution, storage and composting can significantly reduce the active ingredient content. The rate of excretion of chlortetracycline in urine and faeces varies between species. Spreading manure from animals treated on different areas of land each year can prevent accumulation of the active substance in the soil. Manure made from the deep litter of domestic fowls can be used after proper storage.

3.6 Adverse events

None known.

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 its local representative or the national competent authority via the national reporting system.
See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not administer the veterinary medicinal product to pregnant sows.

3.8 Interaction with other medicinal products and other forms of interaction

Absorption of chlortetracycline from the alimentary tract is reduced by calcium, iron, magnesium and zinc salts.

3.9 Administration routes and dosage

The veterinary medicinal product is recommended for oral administration in drinking water.

This veterinary medicinal product may be administered using drinking water containing active chlorine at a maximum concentration of 1 ppm or hydrogen peroxide at a maximum concentration of 35 ppm.

- soft water with or without biocide should be medicated daily.
- hard water without biocide should be medicated daily. Refer to Section 5.1.

For the 1kg pack accurately weigh 200g of powder.

Chickens: 200g of product should be dissolved in 600L of drinking water and administered daily for up to 5 days. This will provide a daily dosage of 20 - 50mg Chlortetracycline HCl/kg depending on water consumption. Dosage may be adjusted to up to 60mg/kg depending upon the severity of infection, by careful calculation of the total bodyweight of the birds and dissolving the requisite amount of the veterinary medicinal product in the quantity of water consumed within 24 hours.

Pigs: In order to achieve the recommended dosage rate of 20 mg Chlortetracycline HCl/kg, 200 g of product should be dissolved in 500 L of water and administered daily for up to 5 days. This will provide medication for 5000 kg of pigs. Allowance for wastage of medicated water and reduced water intake should be made and the necessary adjustment made to the amount of product used.

Medicated water should be prepared daily and any unused water should be discarded safely. Chickens and pigs should have access only to medicated water during treatment.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No specific antidote is available.

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

Pigs:
Meat and offal: 6 days.

Chickens:
Meat and offal: 3 days.
Not for use in laying birds producing or intended to produce eggs for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01AA03

4.2 Pharmacodynamics

Chlortetracycline is a broad spectrum antibiotic of the tetracycline group.
Tetracyclines act by inhibiting protein synthesis, binding reversibly to receptors of the 30S ribosomal subunit of susceptible microbes. The initial binding blocks the later binding of aminoacyl-tRNA to the acceptor site on the mRNA-ribosomal complex, preventing the addition of new amino acids to new peptide chains, inhibiting protein synthesis. Tetracyclines enter the micro-organism by both passive diffusion and active transport mechanisms. Susceptible micro-organisms will concentrate the 5 antibiotic, while resistant strains carry R-factors (typically plasmid borne) which either inhibit the uptake of the drug or causes efflux (pumping) out of the cell. Alternatively, ribosomes may be modified by mutation to prevent tetracycline activity (target modification).
Tetracyclines can also inhibit protein synthesis in the host, but are less likely to reach the concentration required because eukaryotic cells do not have a tetracycline uptake mechanism.
At recommended dosages it has no pharmacological effects on cardio-vascular, nervous or other body systems. Resistance among target pathogens may develop fast due to horizontal transmission (plasmids).

Regional differences in the resistance pattern are present. A strain which is resistant to a tetracycline will also be resistant to other members of the class of tetracyclines.

4.3 Pharmacokinetics

Chlortetracycline hydrochloride is readily absorbed and distributed in the tissues in chickens and pigs. Blood concentrations may be enhanced by administration with citric acid.

When dosed orally it is absorbed into the blood stream, achieving effective concentrations in various tissues including lungs and other respiratory tissues. It is excreted in urine and faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not administer in hard water with biocide.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale (200g bag): 1 year.
Shelf life of the veterinary medicinal product as packaged for sale (1kg bag): 2 years.
Shelf life after first opening the immediate packaging (200g bag): Use immediately.
Shelf life after first opening the immediate packaging (1kg bag): 14 days.
Shelf life after dissolution according to directions: 24 hours.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.
Store in a dry place.
After opening the inner bag of a 1kg pack, seal after use and keep container tightly closed.

5.4 Nature and composition of immediate packaging

200 g and 1kg bag composed of laminated foil.

Package sizes:
5 x 200g laminated foil bags in a cardboard box or a polypropylene bucket.
1 kg laminated foil bag in a polypropylene bucket with a polypropylene or polyethylene snap fit lid.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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 Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10990/053/001

8. DATE OF FIRST AUTHORISATION

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

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).