PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box or Polypropylene bucket with a polypropylene or polyethylene snap fit lid for 5 x 200g; Polypropylene bucket with a polypropylene or polyethylene snap fit lid for 1kg}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chloromed 500 mg/g powder for oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:
465 mg Chlortetracycline (equivalent to 500 mg chlortetracycline hydrochloride)

3. PACKAGE SIZE

200g
1 kg

4. TARGET SPECIES

Chickens (broilers) and pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal period:
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.

8. EXPIRY DATE

Exp. {mm/yyyy}

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.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Univet Ltd.

14. MARKETING AUTHORISATION NUMBERS

UK(GB) Vm 05150/5001
UK(NI) Vm 05150/3001

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {LABEL – 1 Kg and 200g laminated foil}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chloromed 500 mg/g powder for oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:
465 mg Chlortetracycline (equivalent to 500 mg chlortetracycline hydrochloride).

3. TARGET SPECIES

Chickens (broilers) and pigs.

4. ROUTES OF ADMINISTRATION

In drinking water use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
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.

6. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after dissolution according to directions: 24 hours.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Univet Ltd [LOGO]

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:
PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each g contains:

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

A yellow powder.

3. Target species

Chickens (broilers) and pigs.

4. Indications for use

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.

5. Contraindications

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

6. Special warnings

Special warnings:

None.

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.

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

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.

Major incompatibilities
Do not administer in hard water with biocide.

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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 **Major incompatibilities**.

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.

9. Advice on correct administration

Advice to herdsmen:
It is important that you read the instructions before using this veterinary medicinal product.

10. 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.

11. Special storage precautions

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after ‘Exp’. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

UK(GB) Vm 05150/5001
UK(NI) Vm 05150/3001

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.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Univet Ltd
Tullyvin
Cootehill
Co. Cavan
Ireland

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Local representatives and contact details to report suspected adverse reactions:

17. Other information

POM-V

Gavin Hall

Approved: 24 December 2024