Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Chlorsol 50 % Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Chlortetracycline Hydrochloride 50% w/w

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder for oral solution packaged in either 200 g or 2 kg laminated foil sachet.

4 CLINICAL PARTICULARS

4.1 Target Species

Broiler chickens and pigs.

4.2 Indications for use, specifying the target species

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

Chickens: Chlorsol 50 is used in the treatment and control of colibacillosis secondary to infectious bursal disease, chronic respiratory disease caused by *Mycoplasma gallisepticum* and *Escherichia coli*, and *Salmonella enteritidis*, *Salmonella typhimurium* and *Pasteurella multocida* infections.

Pigs: Chlorsol 50 is used in the treatment and control of respiratory diseases associated with *Mycoplasma hyopneumoniae*, *Steptococcus suis* and toxigenic strains of *Pasteurella multocida*. It is also used in the treatment and control of rhinitis due to *Bordetella bronchiseptica* and streptococcal meningitis due to *Streptococcus suis* type II.

4.3 Contraindications

None known

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

Special precautions for use in animals

Once opened, the entire contents of the 200g sachet must be added to the required quantity of water. After opening the inner sachet of a 2kg pack, seal after use and keep container tightly closed. Once inner sachet has been opened, contents must be used within 7 days. Any medicated water, which is not consumed within 24 hours, should be discarded safely.

Chickens and pigs should have access only to medicated water during treatment.

Special precautions to be taken by the person administering the product to animals

Avoid inhalation of dust by wearing a protective mask. 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.

In case of accidental spillage onto the skin or eyes, wash the affected area with clean running water immediately. Seek medical attention if irritation occurs/persists.
Wash hands thoroughly after using this product.

4.6 Adverse reactions (frequency and seriousness)

Not applicable

4.7 Use during pregnancy, lactation or lay

Do not administer Chlorsol 50 to pregnant sows, see also 4.3

4.8 Interaction with other medicinal products and other forms of interactions

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

4.9 Amounts to be administered and administration route

Chlorsol 50 is recommended for oral administration in drinking water. For the 2kg pack a level scoop contains approximately 20g 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 Chlorsol 50 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No specific antidote is available.

4.11 Withdrawal period(s)

Chickens 3 days
Pigs 6 days

Not for use in laying birds producing eggs for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet code: QJ01AA03 Antibacterials for systemic use (chlortetracycline)

5.1 Pharmacodynamic properties

Chlortetracycline hydrochloride is a bacteriostatic antibiotic belonging to the tetracycline group, which acts by inhibition of protein synthesis.

5.2 Pharmacokinetic particulars

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipient:
Anhydrous Citric Acid

6.2 Major incompatibilities

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

6.3 Shelf-life

Powder: The shelf-life of the unopened sachet is 24 months. Once opened the entire contents of a 200g sachet must be used at once. Once inner sachet of 2kg pack has been opened, contents must be used within 7 days.

On dilution: Any medicated water that is not consumed within 24 hours should be discarded safely.

6.4 Special precautions for storage

Store in a dry place.
Do not store above 25°.

6.5 Nature and composition of immediate packaging

The product is available in two pack sizes: A laminated foil sachet containing 200g of the product or a laminated foil sachet containing 2kg of the product supplied in a polypropylene bucket with a polypropylene or polyethylene snap fit lid and 25 ml scoop. The product is a free flowing yellow powder.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused product or waste material should be disposed of in accordance with national requirements, if appropriate.

7 MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited
12 Northbrook Road
Ranelagh
Dublin 6
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8 MARKETING AUTHORISATION NUMBER(S)

VPA10983/047/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th June 2001
Date of last renewal: 5th June 2006

10 DATE OF REVISION OF THE TEXT

August 2019