1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLORTETRACICLINA 20% UCL Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:

Chlortetracycline (as hydrochloride) 200 mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for use in drinking water or liquid feed

4. CLINICAL PARTICULARS

4.1 Target species

Broiler chickens

4.2 Indications for use, specifying the target species

For treating primary and secondary infections, caused by bacteria which are sensitive to chlortetracycline in broiler chickens.

4.3 Contraindications

Do not use in case of hypersensitivity to the active ingredient or to any of the excipients. Do not use in subjects with kidney failure.

Do not use if tetracycline resistance has been shown on the farm.

4.4 Special warnings for each target species

The uptake of medication by animals may be altered because of illness. In case of insufficient feed uptake, animals should be treated parenterally instead using a suitable injectable product prescribed by the veterinarian.

Repeated and prolonged use should be avoided by improving management practices by cleaning and disinfection.

4.5 Special precautions for use

Special precautions for use in animals

Official, national and regional antimicrobial policies should be considered when the product is used.

Particular attention should be paid to improving breeding practices to avoid any stress conditions.

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

Mix thoroughly in drinking water or in liquid feed.

When handling the product, use special protective equipment consisting of protective clothing, gloves and mask, do not inhale, avoid contact with skin and eyes and mucous membranes.

Do not eat, drink or smoke while handling, wash hands after use.

Do not swallow; in case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

In case of accidental contamination with the skin or eyes, wash thoroughly with soap and running water.

People with known hypersensitivity to amoxicillin should avoid contact with the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

Not applicable

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il

4.7 Use during pregnancy, lactation or lay

The chlortetracycline readily diffuses across the placenta and is found in the blood, into the membranes and tissues of the fetus, it is advisable to limit the indispensable use during pregnancy.

To use only accordingly to the benefit-risk assessment by the responsible veterinarian

4.8 Interaction with other medicinal products and other forms of interaction

The absorption of the CTC is reduced by the simultaneous presence of Ca^{++} and Mg^{++} ions, avoiding the simultaneous administration of minerals or products based on calcium and magnesium and using, if possible, a poor supply of the two elements.

Do not use in conjunction with bactericidal antibiotics.

4.9 Amounts to be administered and administration route

Administer orally. The product must be previously dissolved in drinking water or liquid feed.

Broilers:, Daily dosage of 25 - 50mg Chlortetracycline HCl/kg depending on water consumption to be administered through liquid feed or drinking water at concentrations between 0.125-0.250 g of product per Kg of b.w .. depending on the age weight and consumption of food or water of the animals during 3-5 consecutive days.

Route of Administration:

To ensure proper consumption of the chlortetracycline dose per kg/day, the product can be administered in different ways as follows:

The daily dose, calculated on the basis of body weight, can be administered in about half of the water consumed daily. After the complete consumption of the medicated water, administer non-medicated water for the rest of the day.

The product can be administered continuously in the drinking water.

The concentration to be used depends on the body weight and water consumption of the animals and should be calculated according to the following formula:

$$\frac{\text{...mg Chlortetracycline 20\% mg/g powder per kg body weight/day} \times \text{Average body weight Chickens (kg)}}{\text{Average water intake per animal (litres)}} = \text{....mg Chlortetracycline 20\% mg/g powder per litre of drinking water}$$

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. The required dose must be measured with a balance. Medicated water must be renewed every 12 hours.

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

Data not available. Do not exceed the recommended dose.

4.11 Withdrawal period(s)

Broilers 3 days

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibacterials for systemic use, tetracyclines

ATC vet CODE: QJ01AA03

5.1 Pharmacodynamic properties

Chlortetracycline belongs to the group of tetracyclines, chemically related antibiotics and characterized by the presence of a base-tetracyclic nucleus and relatively little toxic.
Chlortetracycline is an antibiotic characterized by a broad antibacterial spectrum comprising schizomycetes, gram-positive and gram-negative bacteria, and some protozoa.
The antibacterial activity at concentrations achievable in therapy is exclusively bacteriostatic.

5.2 Pharmacokinetic particulars

Administered orally, chlortetracycline is adequately but incompletely absorbed by the upper portions of the gastro-intestinal tract: absorption is antagonized and / or delayed by milk and derivatives, by the simultaneous administration of aluminum hydroxide gel and calcium and magnesium salts. Once absorbed, chlortetracycline is rapidly distributed in all organs, particularly in the kidneys, liver, spleen and lungs. The main routes of elimination are renal and bile.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dextrose monhydrate

6.2 Incompatibilities

In the absence of compatibility studies, this 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: 18 months. Shelf-life after first opening the immediate packaging: 30 days
Shelf life after dilution or reconstitution in water according to directions: 12 hours.

6.4. Special precautions for storage

This veterinary medicinal product does not require any special storage conditions. Keep in the original packaging tightly closed to protect it from moisture.

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is packed in paper/polyethylene bags of 5 kg

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

M.P.VET LTD

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8. MANUFACTURER

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9. REGISTRATION NUMBER(S)

083-61-92359

10 DATE OF REVISION OF THE TEXT

Revised January 20221, according to Israeli MoH guidelines