CHLORO-20 POWDER
(Chlortetracycline HCl)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

CHLORO-20 POWDER.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Kg Contains:
Chlortetracycline HCl ……. 200gm

3. PHARMACEUTICAL FORM

Oral Powder.

4. CLINICAL INFORMATION

4.1. Target species

Calf & Chicken.

4.2. Indications for use specifying the target species

For the treatment of bacterial diseases of the respiratory tract caused by pathogens sensitive to chlortetracycline.
Chickens: Respiratory tract infections caused by chlortetracycline-sensitive *Pasteurella multocida*, *Mannheimia haemolytica*, *Chlamydia* and *mycoplasma*.

4.3. Contraindications

Do not use in case of known hypersensitivity to the active ingredient or to any of the other components.
Do not use in animals with severe liver and kidney dysfunction.
Do not use on ruminant cattle.
Do not use if resistance to tetracyclines has been demonstrated.

4.4. Special warnings for each target species

In animals with significantly impaired general condition and/or inappetence, parenteral treatment should be preferred.

4.5. Special precautions for use

Special precautions for safe use in the target species:

Due to widespread resistance to tetracyclines, which is particularly evident in *Streptococci, Pasteurella, Mannheimia haemolytica* or *Bordetella* occur, the sensitivity of the

pathogens identified as the cause must be checked before treatment. When using the veterinary medicinal product, official, national and local regulations on the use of antibiotics must be taken into account.

Use of the veterinary medicinal product deviating from the instructions in the product information may increase the prevalence of chlortetracycline-resistant bacteria and reduce the effectiveness of treatment with other tetracyclines and also with antimicrobial substances of other substance classes.

Since eradication of the causative pathogens may not be achieved, medication should be combined with good farm management, e.g. good hygiene, good ventilation and sufficient housing space for the animals.

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

People with known hypersensitivity to tetracyclines should avoid contact (skin exposure) with the veterinary medicinal product. If inhaled, ingested or in contact with the skin, tetracyclines can cause hypersensitivity (allergy).

To avoid sensitization or contact dermatitis, direct skin contact and inhalation should be avoided during handling, processing and/or use.

- When handling the veterinary medicinal product, the user should wear protective equipment consisting of a suitable protective mask, gloves and suitable safety goggles.
- Avoid contact with skin and eyes. In case of contact with the veterinary medicinal product, rinse immediately and thoroughly with water.
- Do not smoke, eat or drink while handling. Wash hands immediately after Wash after handling the veterinary medicinal product.
- If a skin rash occurs after contact, seek medical advice and swelling of the face, lips, or eyes, or difficulty breathing, are serious symptoms that require immediate medical attention.

Special precautions for environmental protection:
Not applicable.

4.6. Adverse reactions (frequency and seriousness)

Target species: Cattle (Calf), chicken

Indeterminate frequency (Due to missing data, no Frequency can be estimated):	Allergic reactions, anaphylaxis[1] Photodermatitis[2] Liver damage Disturbance of the intestinal flora[3] Renal dysfunction[4] Inhibition of bone calcification, browning of teeth in growth phase[5]

1 In cases of allergic or anaphylactic reactions, discontinue the drug immediately and initiate countermeasures (administration of glucocorticoids, antihistamines, circulatory agents) without delay. 2 In case of intense light exposure (UV radiation) in animals with low skin pigmentation. 3 Prolonged treatment with chlortetracycline may result in disturbances of the intestinal flora or superinfections with resistant bacteria (e.g. *E. coli* or yeasts). 4 In case of disturbed fluid balance 5 when used during the growth period, a strict indication is therefore required
Reporting adverse reactions is important. It allows for continuous monitoring of the tolerability of a veterinary medicinal product. Reports should preferably be submitted by a

veterinarian via the national reporting system to either the marketing authorization holder, its local representative, or the competent national authority. The relevant contact details can also be found in section 16 of the package leaflet.

4.7. Use during pregnancy and lactation or lay

Pregnancy:
The treatment of pregnant and newborn animals requires strict indication, since disturbances in tooth and bone development in fetuses and newborns due to the deposition of chlortetracycline in the tooth and bone tissue of growing animals cannot be ruled out. Use only after appropriate benefit-risk assessment by the attending veterinarian.
Lactation: Do not use in lactating dairy cows.
Legislative term: Do not use in laying birds whose eggs are intended for human consumption.

4.8. Interaction with other veterinary medicinal products and other forms of interaction

The simultaneous administration of preparations containing divalent or trivalent cations (e.g. Ca2+ Mg2+, Fe2+/3+) should be avoided, as antibacterially ineffective chelate complex compounds can form, which, like oral adsorbents, lead to a restriction or prevention of absorption. Chlortetracycline can potentiate the effects of anticoagulants, as well as the neuromuscular blockade of muscle relaxants and narcotics (respiratory paralysis). Chlortetracycline, which has a bacteriostatic effect, should not be used with bactericidal compounds (e.g., penicillins, Aminoglycoside antibiotics) because this may impair the antibacterial efficacy.

4.9. Dosage and administration route

For administration via feed, water or drinking water
The veterinary medicinal product is intended for use in individual animals or for use in groups of animals within a herd.
Dosage:
Calf, chicken: 2 x Daily 30 mg Chlortetracyclin-HCl/kg KGW corresponding to 150 mg of the veterinary medicinal product/kg body weight twice daily
The treatment duration is generally 7 days (max. 10 days).
Administration via drinking water (chicken): When administered via drinking water, the appropriate amount of powder should be completely dissolved in a small amount of fresh water twice daily and added to a portion of the daily drinking water. To ensure complete absorption of the medicated drinking water, the animals to be treated should be denied access to drinking water for two hours prior to treatment. Care should be taken to ensure that the medicated solution is ingested within 4-6 hours. Only after the medicated solution has been completely absorbed should pure drinking water be offered.
To ensure equal water intake for all animals being treated, sufficient drinking space must be provided.
If there is no improvement in the symptoms within 3 days, the diagnosis must be reviewed and, if necessary, a change in therapy.

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

In case of overdose, gastrointestinal symptoms (loss of appetite, vomiting, tympany, indigestion) are to be expected. In such cases, the veterinary medicinal product should be discontinued immediately and symptomatic treatment initiated. Ensure that the animals have an adequate supply of drinking water.

4.11. Restrictions and special conditions of use, including restrictions on the use of antimicrobial and antiparasitic veterinary drugs, in order to reduce the risk of resistance development

Medication administered under the control or supervision of the veterinarian

4.12. Withdrawal period:

Edible tissues: Chicken: 14 days
Do not use on animals whose milk is intended for human consumption. Do not use on animals whose eggs are intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

ATCvet-Code: **QJ01AA03**

5.1. Pharmacodynamics properties

Chlortetracycline has a bacteriostatic effect by inhibiting protein synthesis. Its spectrum of activity includes Gram-positive and Gram-negative aerobic and anaerobic bacteria, as well as mycoplasmas, chlamydia, leptospires, and rickettsiae. However, significant resistance, often strain-specific, is to be expected in many bacteria such as staphylococci, streptococci, *Pasteurella*, *Haemophilus, Bordetella*, some mycoplasmas, corynebacteria, and clostridia, as well as in many enterobacteria (*E. coli*, *Salmonella, Klebsiella,* and others).
Resistance can develop rapidly during therapy, particularly as a result of the transfer of resistance genes through plasmids. Cross-resistance is almost always present within the tetracycline group.

5.2. Pharmacokinetic information

The absorption of chlortetracycline is limited due to its amphoteric molecular nature; oral bioavailability is a maximum of 50% in calves and 20-40% in chickens. Compared to other first-generation tetracyclines, CTC exhibits better tissue penetration. Distribution in the body is uneven, with low concentrations in the central nervous system and placenta. The highest concentrations are reached in the kidneys and liver. Chlortetracycline is fixed in calcifying tissues.
Chlortetracycline undergoes enterohepatic circulation. It is partially inactivated in vivo and excreted via feces and urine, as well as milk and eggs. The biological half-life after oral administration is two hours in chickens and nine hours in calves. It is prolonged in cases of renal insufficiency. There are considerable individual differences in the concentration profiles in vivo.

6. PHARMACEUTICAL INFORMATION

6.1 List of Excipients

Glucose monohydrate

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 mixing into feed: use immediately after mixing

6.4. Special precautions for storage

Store below 25°C in a dry place.
Do not store in the refrigerator or freezer.
Protect from light and moisture.
Keep out of the reach of children.
To be used as directed by the registered veterinary practitioner only.

6.5. Nature and composition of primary conditioning

Pack Size: 100 g, 500 g, 1 kg & 5 kg

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF WASTE MATERIALS
UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS

Any unused veterinary medicinal products or waste materials derived from such medicinal products should be disposed of in accordance with local requirements and placed in appropriate collection and disposal systems for unused or expired medicinal products.

7. MARKETING AUTHORISATION HOLDER

Nawan Laboratories (Pvt.) Ltd.
Plots No. 136-138, Sector-15,
Korangi Industrial Area, Karachi-74900, Pakistan.

8. MARKETING AUTHORISATION NUMBER

Reg. No.: 026416

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 14-10-2000

10. DATE OF REVISION OF THE TEXT

17-02-2025

MANUFACTURED BY:

NAWAN LABORATORIES (PVT) LTD.
136, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan.