CTC-HCl 10% Pulver

100 mg/g, powder for oral administration in cattle (calves), pigs and chickens

Active ingredient: Chlortetracycline hydrochloride

Target species: Cattles, calves, pigs and chickens






Name and address of the marketing authorisation holder:
bela-pharm GmbH & Co KG, Lohner Str. 19, 49377 Vechta - Germany

Statement of the active substance(s) and other ingredient(s):
1.0 g powder contains:
Pharmacological active substance:
Chlortetracycline hydrochloride 100 mg

Indications:
For therapy of infectious diseases of the respiratory- and gastro-intestinal tract (with the exception of systemic *E. coli* and *Salmonella* infections) in *calves*, *pigs*, and *chicken*, caused by bacteria sensitive to chlortetracycline.

Contraindications:
Severe disturbances of hepatic or renal function.
Do not use in ruminating *cattle* (*calves* older than 6 weeks).
Hypersensitivity to tetracyclines.
Resistance to tetracyclines.

Adverse reactions (frequency and seriousness)
The treatment of pregnant and *newborn animals* requires strict indications, as disturbances of dental and skeletal development in the *foetus* and the *newborn*, on the basis of the binding of tetracycline in dental and bone tissue of growing animals can not be excluded.
On corresponding disposition, allergical or anaphylactic reactions may occur. In this case withdraw chlortetracycline immediately and initiate appropriate countermasures (parenteral administration of glucocorticoids and antihistaminics). Gastro-intestinal disturbances with vomiting and diarrhoea may be observed in rare cases when the product is administered to fasting animals. In long-term treatment pay attention to superinfections e.g. with *Candida spp*..
In animals with disturbed fluid balance, the danger of functional disturbance of the kidneys is increased. Chlortetracycline may cause liver damage. During therapy intensive light insolation on skin with poor pigmentation often causes photodermatitis.

Target species:
Cattle (calves), pigs, chicken.

Dosage for each species, route(s) and method of administration:
For administration with the milk / milk substitute in *calves*.
For administration with the feed or drinking water in *pigs*.
For administration with the drinking water in *chickens*.

Calves:
After an initial dose of 20 mg chlortetracycline hydrochloride per kg body weight (b.w.), equivalent to 200 mg CTC-HCl 10% Pulver per kg b.w., a maintenance dose of 10 mg chlortetracycline hydrochloride per kg b.w., equivalent to 100 mg CTC-HCl 10% Pulver per kg b.w. is given twice daily in intervals of 12 hours.

Pigs:
40 mg chlortetracycline hydrochloride per kg body weight (b.w.) per day, divided into:
2 x 20 mg chlortetracycline hydrochloride per kg b.w. daily
equivalent to 2 x 200 mg CTC-HCl 10% Pulver per kg b.w. daily.
The intake of food and water can vary considerably between day and night.

Treatment of single animals (*calves*, *pigs*):
The powder is to be mixed for each application fresh into a part of the feed, the drinking water, the milk or in the ready to use milk substitute, respectively, that a complete mixing is achieved. The prepared medication is to be given immediately and prior to the regular feeding. It has to be ensured that the designated dose is taken up completely.

Treatment of a part of the stock (*chickens*):
For administration with the drinking water of *chickens*:

Chickens:
2 x 40 mg chlortetracycline hydrochloride per kg body weight (b.w.) per day,
equivalent to 2 x 400 mg CTC-HCl 10% Pulver per kg b.w. daily.
The required amount of the powder is to be solved completely and fresh per dosage interval (12 hours) in a small part of the drinking water, and to be given to the drinking water immediately.
To ensure an even water uptake by all animals, sufficient watering places have to be provided.
In case of pasture keeping, the animals should be kept in stables during the treatment.
The dosage has to be adjusted to the actual, real daily intake of drinking water by the animals as this varies in dependence on the age, state of health, purpose of the animals and the way of rearing (e.g. varying ambient temperature, different light patterns).
For the above mentioned dose, the amount of CTC-HCl 10% Pulver to be mixed into the drinking for the animals to be treated is calculated per dosage interval (12 hours) according to the following formula:

$$\frac{\text{400 mg CTC-HCl 10\% Pulver per kg body weight} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily intake of drinking water (l) per animal}} = \text{... mg CTC HCl 10\% Pulver per l of drinking water}$$

Upon completion of the treatment, the watering trough is to be cleaned in a suitable manner to avoid the intake of subtherapeutic, especially resistance-promoting residues of the applied antibiotic.
The duration of treatment is in general 5 days. After cessation of clinical symptoms, the therapy should be continued for 2 more days. Should there be no significant improvement of the state of health after 3 days of treatment, review diagnosis and change therapy, if necessary.

Advice on correct administration:

Special warnings for each target species:

Not indicated.

Special precautions for use in animals:

Because of the high incidence of bacteria resistant to chlortetracycline, especially of *E. coli* in *pigs* and *turkeys*, but as well as in other farm animals, and *Salmonella typhimurium* in *cattle* and *pigs*, if such germ is under suspect, a treatment with chlortetracycline shall only be executed based on the clear susceptibility of the germ given as a result of an antibiogram.

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

Avoid direct skin contact and inhalation due to the risk of sensitisation or contact dermatitis during handling and/or application. For this purpose, wear a dust mask and gloves.

Use during pregnancy, lactation or lay:

The treatment of pregnant and *newborn animals* requires strict indications, as disturbances of dental and skeletal development in the *foetus* and the *newborn*, on the basis of the binding of tetracycline in dental and bone tissue of *growing animals* can not be excluded.

Interaction with other medicinal products and other forms of interaction:

The concomitant administration of products containing bi- or trivalent cations (e.g. Ca^{2+}, Fe^{2+}, Fe^{3+}) has to be avoided, as antibacterial inactive chelates may be formed, which hinders the absorption, just as oral adsorbents do.

There is a potential antagonism between tetracyclines and antibiotics acting bactericidal.

Overdose (symptoms, emergency procedures, antidotes):

Following overdose gastro-intestinal symptoms, as vomiting or tympany, may appear. Withdraw the pharmaceutical immediately.

Overdoses may cause liver damage. On the occurrence of symptoms indicating hepatic or renal damage, stop therapy with CTC-HCl 10% Pulver immediately and initiate therapeutic measures as rehydration and providing electrolytes. Administration of calcium- or magnesium salts or adsorbants may prevent enteral absorption of remaining chlortetracycline.

An early termination of therapy should be done by agreement with the veterinarian treating the animals, as in this way the development of resistant strains is promoted.

Incompatibilities:

To avoid possible incompatibilities do not mix mix with other pharmaceutical products.

Withdrawal period(s):

Calf, *pig*:	edible tissues:	14 days
Chicken:	edible tissues:	14 days
Chicken:	eggs:	10 days

Special storage precautions:

Do not store at temperatures exceeding 30 °C. To protect from light and humidity keep in the original packing and close opened containers carefully.

Keep out of reach and sight of children.

Shelf life after dilution or reconstitution according to directions:
The stability of the medicated drinking water is dependant on the influence of light.
Stability of the medicated drinking water in closed drinking systems: 12 hours.
Stability of the medicated drinking water in open drinking systems: 8 hours.
Stability of the medicated milk or milk substitute: 4 hours.
Solutions of the pharmaceutical in the milk/milk substitute must be prepared immediately prior to its use and are to be fed instantly.
Shelf life after first opening of the container: 14 days
Residuals of the pharmaceutical remaining in the container after the period to be used up is terminated are to be wasted.
Do not use after the expiration date stated on the label.

Special warnings:
None.

Special precautions for the disposal of unused product or waste materials:
Remaining quantities shall be preferably given to pollutant collecting points. When wasted together with the general household waste, it has to be ensured that no misuse of the pharmaceutical is possible. Veterinary pharmaceuticals must not be wasted with waste water or sewage systems. Local regulations for the disposal of pharmaceuticals have to be observed.

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For Veterinary use only.

Available on prescription only!

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