Citrolan® CTC

1000 mg/g, powder for oral administration

for cattle (calves)

Active ingredient: chlortetracyclin hydrochloride



Marketing authorisation holder:
Bela-Pharm GmbH & Co.KG
Lohner Str. 19; 49377 Vechta / Germany

Composition: 1.0 g powder contains:
Pharmacological active substance:
Chlortetracycline hydrochloride 1000 mg

Pharmaceutical form:
powder for oral administration with the milk or milk replacer

Pharmacotherapeutic group:
Antiinfective: tetracycline chemotherapeutic for systemic use

Package size: 1 kg, 5 kg

Target species: Cattle (calves).

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

Contraindications:
Severe disturbances of hepatic or renal function.
Do not use in ruminating cattle.
Hypersensitivity to tetracyclines.
Bacterial resistance to tetracyclines.

Adverse reactions:
Liver damage, gastro-intestinal disturbances.
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 chlortetracycline 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.

Amount(s) to be administered and administration route:
For administration with the milk or milk replacer.
The required amount of powder should be measured with a suitable calibrated scale.

· *Calf:*
After an initial dose of
20 mg chlortetracycline hydrochloride per kg body weight (b.w.),
a maintenance dose of
10 mg chlortetracycline hydrochloride per kg b.w.,
equivalent to 10 mg Citrolan® CTC per kg b.w.
is given twice daily in intervals of 12 hours.
The powder is to be mixed for each application fresh into the ready to use, cooled down milk replacer, 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.
Duration of treatment: 5 days

Withdrawal period(s):
Calf: edible tissues: 14 days

Special warnings:
Special warnings for each target species: Not indicated.

Special precautions for use:
Special precautions for use in animals:
Because of the high incidence of bacteria resistant to chlortetracycline, especially of *Salmonella typhimurium* in cattle, 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.
Should there be no significant improvement of the state of health after 3 days of treatment, review diagnosis and change therapy, possibly an infection with bacteria resistant to chlortetracyclin is present.
In animals with a clearly disturbed general condition and/or animals showing a lack of appetite, a preparation for parenteral administration shall be preferred.

Special safety 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 chlortetracycline in dental and bone tissue of growing animals can not be excluded.

Interaction with other medicinal products and other forms of interaction:
There is a potential antagonism between tetracyclines and antibiotics with bactericidal activity.

Overdose:
Following overdosage 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 Citrolan® CTC 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.

Special precautions for storage:
Store tightly closed, protected from light.
Do not use the medicinal product after the expiry date which is stated on the container and outer package.
Shelf life after opening the container: 12 weeks.
Solutions of the veterinary medicinal product in milk / milk replacer should be prepared immediately before use and fed immediately.
Keep the medicinal product out of the reach of children.

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

Marketing authorisation number: 7910.00.00 (Germany)

For animal treatment only.

Available on prescription only!

Date of revision of the text: 05.01.2022