Ampiciph®

1000 mg/g, powder for oral administration for pigs and chickens (broilers).

Active ingredient: Ampicillin trihydrate

Target species: Pigs and chickens (broilers)



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

Composition:
1 g powder contains:
Pharmacological active substance:
Ampicillin trihydrate 1000 mg
(equivalent to 865.92 g Ampicillin)

Pharmaceutical form:
Powder for oral administration with the drinking water.
White powder.

Pharmacotherapeutic group:
Antiinfective: broad spectrum penicillin as antibiotic for systemical use.

Package size:
250 g, 500 g and 1 kg folding box;
2.5 and 5 kg Card-O-Seal bag.

Target species:
Pig, *chicken* (*broiler*).

Indications:
Treatment of the following infections caused by gram-positive and/or gram-negative germs sensitive to ampicillin in *pigs* and *chickens* (*broiler*):
- infections of the respiratory tract.
- infections of the gastro-intestinal tract.
- infections of the uro-genital tract

Contraindications:
- Treatment of animals hypersensitive to penicillins and cephalosporins,
- severe renal dysfunction with anuria and oliguria,
- presence of ß-lactamase producing germs,
- administration to *ruminant animals* and *horses*.
- Do not use in *laying hens*, when the eggs are intended for human consumption.
- Do not use in *guinea pigs*, *hamsters*, *rabbits*, and other *small rodents*.

Adverse reactions:
Allergic reactions (allergic skin reactions, anaphylaxis).
If allergic reactions occur, discontinue the treatment with Ampiciph® immediately and treat symptomatically.
Countermeasures to be taken if allergic reactions occur:
For anaphylaxis: epinephrine (adrenaline) and glucorticoids i.v.
For allergic skin reactions: antihistaminics and/or glucorticoids.

Dosage for each species, route and method of administration:
Powder for administration with the drinking water.
1000 mg Ampiciph® contain 1000 mg Ampicillin trihydrate
For treatment of a part of the stock:
Pigs:
10 mg Ampiciph® /kg b.w. 3-4 times a day or
2 x 20 mg Ampiciph® /kg b.w. daily.

Broiler:
200 mg Ampiciph® / kg b.w. per day or
2 x 100 mg Ampiciph® / kg b.w. daily.

It has to be ensured that the provided dose is taken in completely.
The intake of feed and drinking water can vary considerably between day and night time.
Dissolve the required amount of powder completely and fresh for every dosage interval (12 hours) in a small part of water and add to the drinking water. Maximal 5 g Ampiciph® solve in 1 litre of drinking water.
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).
For the above mentioned dose, the amount of Ampiciph® to be mixed into the drinking water for the animals to be treated has to be calculated according to the following formula per dosage interval (12 hours):

For *pigs*:

$$\frac{\text{20 mg Ampiciph® per kg body weight/day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily intake of drinking water (l) per animal}} = \text{... mg Ampiciph® per litre drinking water}$$

For *broiler*:

$$\frac{\text{100 mg Ampiciph® per kg body weight/day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily intake of drinking water (l) per animal}} = \text{... mg Ampiciph® per litre drinking water}$$

Prepare the medicated drinking water two times a day. Only freshly prepared solutions must be used.
To ensure an equable water intake by all animals to be treated, sufficient watering places have to be provided. When keeping on pasture, the animals should be housed during the treatment period.
To avoid a reduced resorption of the antibiotic, Ampiciph® should be administered, if possible, to hungry animals, at minimum one hour before or two hours after feeding.
The treatment is to be continued for 3 to 5 days. After subside of the symptoms, the application of the veterinary medicinal product shall be continued for 2 additional days.
After conclusion of the treatment, the drinking equipment has to be cleaned thoroughly in a suitable manner to avoid the intake of subtherapeutic, especially resistance-causing residual amounts of the applied antibiotic.

Should there be no significant improvement of the state of health after 3 days of treatment, review the diagnosis and change the therapy, if necessary.
In animals with a clearly disturbed general condition and/or animals showing a lack of appetite, a preparation for parenteral administration shall be preferred.

Withdrawal period(s):

Pig:	edible tissues:	4 days
Broiler:	edible tissues:	6 days

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

Special precautions for use:
Special precautions for use in animals:
Prior to the use of Ampiciph, the susceptibility of the germs shall be ensured by a susceptibility testing. Because of the high resistance rates of *E. coli* and *Salmonella spp*. this is particularly indicated for infections of the gastro-intestinal tract.
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:
Not indicated.
Interaction with other medicinal products and other forms of interaction:
Regarding the antibacterial activity, an antagonism between penicillins and chemotherapeutic agents with instantaneous bacteriostatic activity (e.g. tetracyclines, macrolids, or lincomycin) is possible.
Penicillins are incompatible with heavy metal ions, amino acids, ascorbic acid, vitamin B-complex and heparin.
Overdose:
Central nervous symptoms of excitement and spasms may occur after overdose. Immediately discontinue the treatment with Ampiciph and treat symptomatically (administration of benzodiazepines or barbiturates).
Incompatibilities:
Mixing with other medicinal products should be avoided due to possible incompatibilities.

Special storage precautions:
Keep out of reach and sight of children.
Shelf life after first opening of the container: 7 days.
Residuals of the pharmaceutical remaining in the container after the period to be used up is terminated are to be wasted.
Stability of the medicated drinking water: 12 hours.
Do not use after the expiration date stated on the label.

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.

Date on which the package leaflet was last approved: 11.09.2009

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For animal treatment only.

Available on prescription only!