

Triamox 100 W

114.8 mg/g, powder for oral administration
with the feed, the drink or the drinking water

Active ingredient: amoxicillin trihydrate

Target species: Calf and pig

Name and address of the marketing authorisation holder:

bela-pharm GmbH & Co. KG, Lohner Str. 19, 49377 Vechta - Germany

Composition:

1 g powder contains:

Pharmacological active substance:

Amoxicillin trihydrate 114.8 mg
(equivalent to 100 mg amoxicillin)

Pharmaceutical form:

Powder for administration with the feed, the drink or the drinking water.
White, crystalline powder.

Pharmacotherapeutic group:

β -lactam antibiotic, penicillin.

Target species:

Calf, pig.

Indications:

Treatment of the following infections caused by gram-positive and/or gram-negative germs sensitive to amoxicillin:

Pigs, and piglets:

- infections of the lung (except for *piglets*) and the respiratory tract;
- infections of the gastro-intestinal tract.

Calves:

- infections of the gastro-intestinal tract.

Contraindications:

Treatment of animals hypersensitive to penicillins and cephalosporins, severe renal dysfunction with anuria and oliguria, presence of β -lactamase producing germs, administration to ruminant animals and *horses*, oral administration in *rabbits, guinea pigs, hamsters* and other *small rodents*.

Do not use in animals with known hypersensitivity to penicillins and other substances of the β -lactam group. Do not use concomitantly with antibiotics acting bacteriostatic.

Adverse reactions:

Allergic reactions (allergic skin reactions, anaphylaxis).

If allergic reactions occur, discontinue the treatment with Triamox 100 W immediately.

Countermeasures, which have to be taken in case of an allergic reaction:

In anaphylaxis: adrenaline and/or glucocorticoids.

In allergic skin reactions: antihistaminics and/or glucocorticoids.

Occasionally disturbances of the gastro-intestinal tract (vomiting, diarrhoea, inappetence) may be observed.



Triamox 100 W

Dosage for each species, route and method of administration:

For administration with the food or the drinking water of *swine*.

For administration with the drink in *calves*.

Calves:

2 x 20 mg amoxicillin / kg b.w. / day, equivalent to

2 x 200 mg Triamox 100 W / kg b.w. / day, equivalent to

2 x 10 g Triamox 100 W / 50 kg b.w. / day.

twice daily in intervals of 12 hours.

Pigs:

2 x 20 mg amoxicillin / kg b.w. / day, equivalent to

2 x 200 mg Triamox 100 W / kg b.w. / day.

The intake of feed and drinking water can vary considerably between day and night time.

For the treatment with the drink in *calves* and the food in *swine*:

The appropriate quantity of powder is to be mixed into a small amount of the food of *swine* or the drink of *calves* (when using a milk replacer, the powder is to be mixed in the ready-to-use, cooled down milk replacer) so that a complete mixture is obtained.

This mixture is to be given immediately to the *pigs* prior to the actual feeding. It has to be ensured that the prescribed dose is taken up completely.

For the treatment of parts of the stock with the drinking water in *swine*:

When administered with the drinking water, the required amount of powder is solved completely and fresh at every dosage interval (12 hours) in a small part of water and added to the drinking water.

To ensure an equable water intake by all animals to be treated, sufficient watering places have to be provided.

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 or different light patterns).

For the above mentioned dose, the amount of Triamox 100 W 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 of 12 hours:

Pigs:

200 mg Triamox 100 W

per kg body weight

per dosage interval

x

average body weight (kg)

of animals to be treated

average intake of drinking water (l)

per animal per dosage interval

= ___ mg Triamox 100 W per

litre of drinking water

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 to 3 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, residual amounts of the applied antibiotic supporting resistance formation.

Triamox 100 W

Advice on correct administration:

Special warnings for each target species:

None.

Special precautions for use:

Special precautions for use in animals:

Prior to the use of Triamox 100 W the sensitivity of the causative germs must be tested by an antibiogram. Due to high resistance rates of *E. coli* and *Salmonella* spp. against amoxicillin, this is of special importance for the treatment of gastro-intestinal infections.

Should there be no significant improvement of the pathological state after 3 days of treatment, review the diagnosis and change the therapy, if necessary.

In animals with clearly disturbed general state of health, the parenteral administration of a pharmaceutical 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:

Not indicated.

Interaction with other medicinal products and other forms of interaction:

Mixing with other medicinal products should be avoided due to possible incompatibilities. Galenic incompatibilities have been observed with heavy metals and oxidants.

Overdose:

Following overdose central nervous excitation and cramps may occur. Discontinue the treatment with Triamox 100 W immediately and treat symptomatically (administration of barbiturates).

An untimely stop of therapy shall only be done after consultation of the veterinarian, as the development of resistant bacterial strains may be promoted.

Incompatibilities:

Avoid mixing with other medicinal products due to the risk of possible incompatibilities.

Withdrawal period(s):

Calf: edible tissues: 3 days

Pig: edible tissues: 1 day

Special storage precautions:

Store in well-closed containers at temperatures not exceeding 25 °C.

Keep out of reach and sight of children.

Stability of the medicated drinking water: 12 hours

Stability of the medicated milk / drink: 12 hours

Solutions of the pharmaceutical in the drink must be prepared immediately prior to its use and must be fed instantly.

Do not use after the expiration date stated on the label.

Triamox 100 W

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: 04.10.2010

Marketing authorisation number: 12992.00.00 (Germany)

For animal treatment only.

Available on prescription only!