

ΠΑΡΑΡΤΗΜΑ 1: ΠΕΡΙΛΗΨΗ ΤΩΝ ΧΑΡΑΚΤΗΡΙΣΤΙΚΩΝ ΤΟΥ ΠΡΟΪΟΝΤΟΣ

1. Name of the veterinary medicinal product:

Amoxicillin trihydrate 11.5%, 100 mg/g, powder for oral administration via the drinking water for cattle and pigs.

Amoxicillin as amoxicillin Trihydrate.

2. Qualitative and quantitative composition:

1 g powder contains:

Active substance(s):

Amoxicillin	100.0 mg
As amoxicillin Trihydrate	114.8 mg

Excipients(s):

For a full list of Excipients, see section 6.1.

3. Pharmaceutical form:

Powder for oral administration via the drinking water

4. Clinical particulars:

4.1 Target specie(s):

Cattle, pig.

4.2 Indications for use, specifying the target species:

For treatment of the following diseases, caused by Amoxicillin-sensitive Gram-positive and/or Gram-negative pathogens:

Calf: infections of the gastrointestinal tract.

Pig: infections of the gastrointestinal tract, the lungs and the respiratory tract.

Piglet: infections of the gastrointestinal tract.

The administration of Amoxicillin trihydrate 11.5% should be done with regard of an antibiogram.

4.3 Contraindications:

Do not use in case of:

- Rabbits, guinea pigs, hamsters, and other small rodents.
- Animals hypersensitive to penicillin's and cephalosporins.
- Severe renal dysfunction accompanied with anuria and oliguria.
- Case of β -lactamase producing pathogens.
- Ruminating animals by oral administration.

4.4 Special warnings for each target species:

Not known.

4.5 Special precautions for use:

For avoidance of any sensitisation or contact dermatitis, avoid direct skin contact and inhalation during preparation and/or administration of Amoxin.
Use dust mask and gloves.

Special precautions for use in animals:
Not known.

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

4.6 Adverse reactions (frequency and seriousness):

Allergic reactions (allergic skin reactions, anaphylaxis).
In case of evidence of allergic reactions, stop immediately treatment with Amoxicillin trihydrate 11.5%.
Emergency procedures in case of allergic reactions:
Anaphylaxis: epinephrine (adrenaline) and glucocorticoids i.v.
Allergic skin reactions: antihistaminics and/or glucocorticoids.

4.7 Use during pregnancy, lactation or lay:

Laboratory studies in rats and mice have not produced any evidence of teratogenic or foetotoxic effects.

4.8 Interaction with other medicinal products and other forms of interaction:

Do not mix with other pharmaceutical products to avoid any incompatibilities. Regarding antibacterial activities, a potential antagonism between penicillins and chemotherapeutics with instantaneous bacteriostatic activity is possible.

4.9 Amounts to be administered and administration route:

By oral administration via the drinking water
Calf, pig and piglet: 20 mg Amoxicillin/kg b.w.
(equivalent to 200mg Amoxicillin trihydrate 11.5%
per kg b.w.) Twice daily

The necessary quantity of powder has to be completely dissolved in a small volume of fresh drinking water every day and administered immediately. It has to be ensured that the intended dose will be completely administered. To enable the same water intake for all animals, sufficient drinking places must be available. In outdoor keeping, the animals should be kept in the stable during treatment.

For treatment of part of a flock:
Dosage has to be done according actual, daily water intake of the animals which depends on age, health status, usage and keeping (e.g. different temperature of the surrounding area). For the above- mentioned dosage,

the mixing of Amoxicillin trihydrate 11.5% in the drinking water is calculated as follows:

$$\frac{400 \text{ mg Amoxicillin trihydrate 11.5\% per kg b.w./day} \times \text{mean b.w. (kg) of treated animals}}{\text{mean daily water intake (l)/animal}} = \text{mg Amoxicillin trihydrate 11.5\% per l drinking water}$$

A level measuring spoon (15 ml) contains approximately 12 g Amoxicillin trihydrate 11.5%

After administration, watering equipment has to be cleaned in suitable manner to avoid intake of subtherapeutic, especially resistance enabling residues of the antibiotic.

Duration of treatment: 3 – 5 days

After ease of clinical signs, should be administered for at least further 2 days.

If after 3 days of treatment no signs of improvement are evident, diagnosis should be reconsidered and if necessary, therapy should be changed. In animals with severe impaired general health and/or in animals with inappetence, treatment with parenteralia is preferable.

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

After overdosage, central nervous signs of excitation and cramps may be apparent. Stop immediately with administration of Amoxicillin trihydrate 11.5% and continue with symptomatic treatment (barbiturates).

4.11 Withdrawal period(s):

Edible tissues: Calf: 11 days
Pig: 3 days

5. Pharmacological particulars

5.1 Pharmacodynamic properties:

ATCvet Code: QJ01CA04

Pharmacotherapeutic group: amoxicillin

Amoxicillin shows in vitro as well as in vivo a broad spectrum of activity against Gram-positive and Gram-negative bacteria. Like other penicillins, its mode of action is relied to the inhibition of the cell wall synthesis.

Amonicillin is not safe from β -lactamases. The development of resistant strains occurs in vitro in all penicillins slowly and gradually. Cross resistance may occur with other penicillins but is only of practical

importance in case of Staphylococcus. In Escherichia coli and Salmonella typhimurium, development of resistance may be expected.

5.2 Pharmacokinetic particulars:

Amoxicillin is stable against gastric acid. The absorption rate following oral administration is 74 – 92 %. The plasma concentration is 1.5 to 3 times higher than a comparable dose of Ampicillin given orally. In contrast to ampicillin, concomitant feed intake has no impact on amoxicillin absorption. Amoxicillin is bound by 13 – 20 % to plasma proteins.

Amoxicillin is well-distributed in tissues (liver, lung, muscle, bone) and body liquids (bile, ascites, pleural liquid, synovial liquid). Amoxicillin may not pass the intact blood-brain barrier, but it may be determined in the pathogen liquor cerebrospinalis. In case of meningitis, the concentration of amoxicillin in the liquor cerebrospinalis reaches 10 – 60% of the corresponding plasma values. Amoxicillin passes the placental barrier.

In dogs and cats, the half-life ranges between 45 and 60 minutes, in cattle 90 minutes. Amoxicillin is mainly excreted renal by tubular secretion, 50 – 75 % in the unchanged form and by 20 – 30 % as inactive metabolites (hydrolysis of penicillic acid). Rate of glomerular filtration is comparatively limited. Amoxicillin is excreted via bile but reabsorbed due to enterohepatic circulation, resulting in neglectible excretion via faeces.

6. Pharmaceutical particulars

6.1 List of Excipients:

Lactose monohydrate

6.2 Incompatibilities:

With sulphonamides, heavy metal ions and oxidation reagents galenic incompatibilities exist.

6.3 Shelf-life:

3 years

6.4 Special precautions for storage:

Store below +25°C. Keep the container tightly closed. Protection from light and moisture.

6.5 Nature and composition of immediate packaging:

1 kg HDPE plastic container

50 g aluminium foil sachet

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product should be disposed preferably at collecting points for pollutants. When disposed with the general household waste, it has to be ensured that no misuse is possible. Veterinary medicinal products must not be disposed with the waste water or sewerage.

7. Marketing authorisation holder:

Demetrios Christoforou Ltd

Tseriou Avenue 169

2048,Strovolos,Nicosia

8. Marketing authorisation number:

16667

9. Date of first authorisation/Renewal of the authorisation:

10. Date of revision of the text:

11. Prohibition of sale, supply and/or use:

12. Legal status:

On prescription