Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

AMOXICILLIN GLOBAL VET HEALTH 500 mg/g, powder for use in drinking water for chickens, turkeys, ducks and pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:
Active substance:
Amoxicillin 436 mg
(equivalent to 500 mg of amoxicillin trihydrate)
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for use in drinking water
A white powder.
Clear and colourless liquid when in solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens, turkeys, ducks and pigs.

4.2 Indications for use, specifying the target species

Treatment of infections in chickens, turkeys and ducks caused by bacteria susceptible to amoxicillin.
Pigs: For the treatment of pasteurellosis caused by *Pasteurella multocida* susceptible to amoxicillin.

4.3 Contraindications

Do not administer to rabbits, guinea pigs, hamsters, horses, gerbils or any other small herbivore.
Do not use in animals with known hypersensitivity to penicillins or other β-lactam antibiotics or to the excipient.
Do not administer to animals with renal disease including anuria or oliguria.

4.4 Special warnings for each target species

Pigs: The uptake of medication by animals may be altered as a consequence of illness. In case of insufficient water uptake, animals should be treated parenterally instead using a suitable injectable product prescribed by the veterinarian.

4.5 Special precautions for use

Special precautions for use in animals

Not effective against beta-lactamase producing organisms.
Official, national and regional antimicrobial policies should be taken into account when the product is used.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the amoxicillin and may decrease the effectiveness of the treatment.

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

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
Handle this product with great care to avoid exposure, taking all recommended precautions.
If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.
Avoid inhalation of dust. Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143.
Wear gloves during preparation and administration of medicated water or liquid feed.
Wash any exposed skin after handling the product or medicated water or feed. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Penicillins and cephalosporins may cause hypersensitivity reactions which may occasionally be serious. Rarely, gastro-intestinal tract signs associated with alteration of the intestinal flora (for example, loose stools, diarrhoea) may occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats have not produced any evidence of a teratogenic effect due to the administration of amoxicillin.
The safety of the veterinary medicinal product has not been established during pregnancy or lactation in sows. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interactions

The product should not be administered with antibiotics that have a bacteriostatic mode of action, such as tetracyclines, macrolides, sulphonamides.

4.9 Amounts to be administered and administration route

For administration in drinking water.
Prepare the solution with fresh potable water immediately before use.
Any medicated water which is not consumed within 24 hours should be discarded and the medicated drinking water replenished.
In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being treated.

Use the following formula in order to calculate the concentration of the product (mg) per litre of drinking water:

$$\frac{\textit{Dose (mg product per kg body weight per day)} \quad X \quad \textit{mean body weight (kg) of animals to be treated}}{\textit{mean daily water consumption (litre) per animal per day}} = \_\_\_ \textit{ mg product per litre drinking water}$$

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. The uptake of medicated water depends on the clinical condition of the animal. In order to obtain the correct dosage the concentration of amoxicillin has to be adjusted taking into account water intake.

The maximum solubility of the product was only demonstrated at 5 g/L at 20ºC. Below 20ºC and above 5 g/L, the product cannot be satisfactorily dissolved. For stock solutions and when using a proportioner, take care not to exceed the maximum solubility which can be achieved under the given conditions. Adjust the flow rate settings of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated.
After the end of the medication period, the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

Chickens:
The recommended dosage is 15 mg amoxicillin trihydrate per kg bodyweight per day (corresponding to 30 mg product/kg bodyweight/day).
The total period of treatment should be for 3 days or in severe cases for 5 days.

Ducks
The recommended dosage is 20 mg amoxicillin trihydrate per kg bodyweight per day (corresponding to 40 mg product/kg bodyweight/day) for 3 consecutive days.

Turkeys
The recommended dosage is 15-20 mg amoxicillin trihydrate per kg bodyweight per day (corresponding to 30 - 40 mg product/kg bodyweight/day) for 3 days or in severe cases for 5 days.

Pigs
For the medication of pigs, the product may be administered via the drinking water or administered by addition to liquid feeds produced with commercial feed. It may not be used in dry feeds.

1. Administration in drinking water
Administer in the drinking water to give 20 mg amoxicillin trihydrate per kg bodyweight (corresponding to 40 mg product/kg bodyweight/day) daily for up to 5 days.
Prepare the solution by carefully mixing the product in the requisite quantity of fresh potable water immediately before use.
The dose should be administered at approximately 24 hourly intervals for up to 5 days.
Any medicated water which is not consumed within 24 hours should be discarded and the medicated drinking water replenished.

In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being on treatment.

2. Administration in liquid feed
Administer in liquid feed to give 20 mg amoxicillin trihydrate per kg bodyweight (corresponding to 40 mg product/kg bodyweight/day) daily for up to 5 days.
Medicated feed should be freshly prepared on at least 3 occasions per day over the treatment period. The daily dose should be calculated based on the number of animals and average weight and then divided by the number of feed lots prepared in the day.
Medicated liquid feed should be prepared with fresh potable water.
After adding the product to some or all of the water needed to make the liquid feed, ensure the product is fully dissolved. Dissolution of the product can take up to 10 minutes. This medicated water can then be mixed with the dry complete meal and if appropriate, the remaining water. The system used should ensure that the medicated water is evenly distributed into the feed. Once prepared the final medicated liquid feed should be fed to the pigs immediately.
The medicated liquid feed should not be fermented and should not be stored.
Stability of amoxicillin in all commercial feeds has not been established. In order to ensure that any loss of amoxicillin activity is minimized, the quantity of medicated liquid feed prepared should not exceed the amount of feed which will be consumed within 4 hours.
Any medicated liquid feed which is not consumed within 4 hours should be discarded.
Although restricted access to other water supplies would help ensure medicated liquid feed is consumed, separate clean potable water should remain available at all times for welfare reasons.

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

No problems with overdosage have been reported. Treatment should be symptomatic and no specific antidote is available.

4.11 Withdrawal period(s)

Meat and offal:

Chickens: 1 day
Ducks: 9 days
Turkeys: 5 days
Pigs: 2 days

Not authorised for use in laying birds producing eggs for human consumption and within 3 weeks of onset of laying.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: antibacterials forsystemic use, beta-lactam antibacterials, Penicillins.
ATCvet Code: QJ01CA04

5.1 Pharmacodynamic properties

Amoxicillin is a time-dependent bactericidal antibiotic which acts by inhibiting the synthesis of bacterial cell walls during bacterial replication. It inhibits the formation of bridges between the chains of linear polymers constituting the peptidoglycan cell wall of Gram positive bacteria.
Amoxicillin is a broad-spectrum penicillin. It is also active against a limited range of Gram negative bacteria on which the outer layer of the bacterial cell wall is composed of lipolysaccharide and proteins.
There are three main mechanisms of resistance to beta-lactams: beta-lactamase production, altered expression and/or modification of penicillin binding proteins (PBP), and decreased penetration of the outer membrane. One of the most important is the inactivation of penicillin by beta-lactamase enzymes produced by certain bacteria. These enzymes are capable of cleaving the beta-lactam ring of penicillins, making them inactive. The beta-lactamase could be encoded in chromosomal or plasmidic genes.
Cross-resistance is observed between amoxicillin and other penicillins, particularly with aminopenicillins.
The use of extended spectrum beta-lactam drugs (e.g. aminopenicillins) might lead to the selection of multi-resistant bacterial phenotypes (e.g. those producing extended spectrum beta-lactamases (ESBLs)).

5.2 Pharmacokinetic particulars

Amoxicillin is well absorbed following oral administration and it is stable in the presence of gastric acids. Excretion of amoxicillin is mainly in the unchanged form via the kidneys to give high concentration in renal tissue and urine.
Amoxicillin is well distributed in body fluids.
Studies in birds have indicated that amoxicillin is distributed and eliminated more rapidly than in mammals.
Biotransformation appeared a more important route of elimination in birds than in mammals.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid, anhydrous

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after dilution or reconstitution in water according to directions: 24 hours.

Shelf life after incorporation into liquid feed: 4 hours.
Shelf-life after first opening the immediate packaging: 7 days

6.4 Special precautions for storage

Do not store above 25º C. Store in a dry place.
Keep the bags tightly closed.
Protect from light.

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is packed in thermo-sealed polyethylene / aluminium / polypropylene bags of 100 g, 200 g, 500 g and 1 kg.
Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

GLOBAL VET HEALTH SL
c/Capcanes, n° 12-bajos
Polígon Agro-Reus
REUS 43206
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA10477/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 December 2015

10 DATE OF REVISION OF THE TEXT

July 2019