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)

Excipient:

Qualitative composition of excipients and other constituents
Citric acid, anhydrous

A white powder.
Clear and colourless liquid when in solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens, turkeys, ducks and pigs.

3.2 Indications for use for each target species

Chickens, turkeys and ducks: for the treatment of infections caused by bacteria susceptible to amoxicillin.

Pigs: for the treatment of pasteurellosis caused by *Pasteurella multocida* susceptible to amoxicillin.

3.3 Contraindications

Do not use in the presence of ß-lactamase-producing bacteria.

Do not use in rabbits, guinea pigs, hamsters, gerbils or any other small herbivores.

Do not use in horses.

Do not use in cases of hypersensitivity to penicillins or other substances from the beta-lactam group or to any of the excipients.

Do not use in animals with renal disease including anuria or oliguria.

3.4 Special warnings

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.

The use of the product should be combined with good management practices e.g. good hygiene, proper ventilation, no overstocking.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

People with known hypersensitivity to penicillins should avoid contact with the veterinary medicinal product.

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.

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.

Wash any exposed skin after handling the product or medicated water or feed. Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens, turkeys, ducks and pigs.

Rare (1 to 10 animals / 10 000 animals treated):	Hypersensitivity reaction[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Disorder of gastrointestinal flora (e.g. loose stools, diarrhoea)[2]

[1] In the case of allergic reactions, treatment should be discontinued, and symptomatic treatment should be initiated.
[2] Associated with alteration of the intestinal flora.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

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 in accordance with the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

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

Synergism occurs with ß-lactam antibiotics and aminoglycosides.

3.9 Administration routes and dosage

In drinking water or feed use.
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:

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

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 20 ºC. Below 20 ºC 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 drinking water or administered by addition to liquid feeds produced with commercial feed. It may not be used in dry feeds.

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

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.
The veterinary medicinal product is to be administered only for the treatment of individually fed animals or a small group of animals where the intake by individual animals can be effectively controlled.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Amoxicillin has a wide safety margin. No overdose symptoms have been reported. Treatment should be symptomatic and no specific antidote is available.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Meat and offal:
Chickens: 1 day.
Ducks: 9 days.
Turkeys: 5 days.
Pigs: 2 days.
Not for use in laying birds producing eggs for human consumption and within 3 weeks of onset of laying.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01CA04.

4.2 Pharmacodynamics

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)).

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products, feed additives or other substances used in drinking water.

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

5.2 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.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is packed in thermo-sealed polyethylene / aluminium / polypropylene bags.

100 g.
200 g.
500 g.
1 kg.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

GLOBAL VET HEALTH, S.L.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10477/002/001

8. DATE OF FIRST AUTHORISATION

04/12/2015

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

21/03/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).