ANNEX III

LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label for presentations: 100 g, 200 g, 500 g and 1 kg

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

Amoxicillin trihydrate

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

Active substance:
Amoxicillin 436 mg
(Equivalent to 500 mg of amoxicillin trihydrate)

A white powder.
Clear and colourless liquid when in solution

3. PHARMACEUTICAL FORM

Powder for use in drinking water

4. PACKAGE SIZE

100 g
200 g
500 g
1 kg

5. TARGET SPECIES

Chickens, turkeys, ducks and pigs

6. INDICATIONS

7. METHOD AND ROUTES OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal periods:

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.

9. SPECIAL WARNINGS, IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions.
See package leaflet for user warnings.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
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.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Global Vet Health SL
C/Capçanes, nº12-baixos
Polígon Agro-Reus
Reus 43206
Spain

16. MARKETING AUTHORISATION NUMBER

Vm 36167/4004

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Global Vet Health SL
C/Capçanes, nº12-baixos
Polígon Agro-Reus
Reus 43206
Spain

Manufacturer responsible for batch release:
SP Veterinaria SA
Ctra Reus Vinyols km 4.1
Riudoms (43330)
Spain

2. 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

Amoxicillin trihydrate

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each gram contains:

Active substance:
Amoxicillin 436 mg
(Equivalent to 500 mg of amoxicillin trihydrate)

A white powder.
Clear and colourless liquid when in solution

4. INDICATION(S)

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.

5. 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 known cases of hypersensitivity to penicillins or other substances from the beta-lactam group or to the excipient.

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

6. ADVERSE REACTIONS

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

In the case of allergic reactions, treatment should be discontinued and symptomatic treatment should be initiated.

Alternatively you can report via your national reporting system {national system details}".

7. TARGET SPECIES

Chickens, turkeys, ducks and pigs.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION AND ADVICE ON CORRECT ADMINISTRATION

For use in drinking water or liquid feed.
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:

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

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.

<u>Administration in drinking water</u>
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

<u>Administration in liquid feed</u>
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.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD

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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25º C. Store in a dry place.
Keep the bags tightly closed. Protect from light.
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.
Do not use this veterinary medicinal product after the expiry date which is stated on the bag after “EXP”. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

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.

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

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 this label may increase the prevalence of bacteria resistant to the amoxicillin and may decrease the effectiveness of the treatment.

User warnings:

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.

Pregnancy/Lactation/Lay/Fertility:
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.

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 β-lactam antibiotics and aminoglycosides.

Overdose (symptoms, emergency procedures, antidotes):
Amoxicillin has a wide safety margin. No overdose symptoms have been reported. Treatment should be symptomatic and no specific antidote is available.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2020

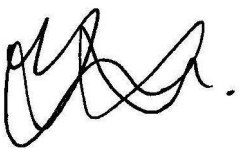
15. OTHER INFORMATION

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.

For animal treatment only. To be supplied only on veterinary prescription.

For any information about this Veterinary Medicinal Product, please contact the local representative of the Marketing Authorisation Holder.



Approved: 15 December 2020