SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HUVAMOX 800 mg/g powder for use in drinking water for chickens, turkeys, ducks and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram (g) contains:

Active substance:
Amoxicillin ……697 mg
(equivalent to 800 mg of amoxicillin trihydrate).

Excipients:

Qualitative composition of excipients and other constituents
Sodium carbonate
Sodium citrate
Silica colloidal hydrated

White to slightly yellow powder.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (broiler, pullet, for reproduction), ducks (broiler, for reproduction), turkeys (broiler, for reproduction) and pigs.

3.2 Indications for use for each target species

In chickens, turkeys and ducks: Treatment of infections caused by bacteria susceptible to amoxicillin.

In pigs**:** For the treatment of pasteurellosis caused by *Pasteurella multocida* susceptible to amoxicillin.

3.3 Contraindications

Do not use in horses, rabbits, guinea pigs, hamsters, gerbils or any other small herbivore given that amoxicillin, as for all aminopenicillins, has a deleterious effect on caecal bacteria.
Do not use in ruminants.
Do not use in animals with hypersensitivity to penicillins or other ß-lactam antibiotics or to any of the excipients.

Do not use in animals with renal disease including anuria or oliguria.
Do not use in the presence of ß-lactamase-producing bacteria.

3.4 Special warnings

The veterinary medicinal product is not effective against beta-lactamase producing organisms.
Cross-resistance has been shown between amoxicillin and other penicillins, in particular amino-penicillins in bacteria susceptible to amoxicillin. Use of the veterinary medicinal product/amoxicillin should be carefully considered when susceptibility testing has shown resistance to penicillins because its effectiveness may be reduced.
The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient water uptake, animals should be treated parenterally instead using a suitable injectable veterinary medicinal product prescribed by the veterinarian.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level. Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies. Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to amoxicillin and may decrease its effectiveness and the effectiveness of treatment with other penicillins, due to the potential for cross-resistance.
Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.
The antimicrobial should not be used as part of heard health programmes.
Not for use for prophylaxis.

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 beta-lactam antibiotics should avoid handling the veterinary medicinal product.
Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions.
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 hands after use. Wash any exposed skin after handling the veterinary medicinal product or medicated water or feed.
In the event of eye or skin contact , rinse the affected area with large amounts of clean water.
Do not smoke, eat or drink while handling the veterinary medicinal product. In case of accidental ingestion, immediately rinse the mouth with water and seek medical advice.
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.

Special precautions for the protection of the environment:
Not applicable

3.6 Adverse events

Chickens, ducks, turkeys and pigs:

Undetermined frequency (cannot be estimated from the available data)'	Hypersensitivity reaction (varying from allergic skin reaction to anaphylactic shock) Digestive tract disorders (vomiting, diarrhoea)

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 shown evidence of teratogenic effects.
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

The veterinary medicinal product should not be administered with antibiotics that have a bacteriostatic mode of action, such as tetracyclines, macrolides, sulphonamides as they can antagonise the bactericidal effect of penicillins.
Do not use simultaneously with neomycin since it blocks the absorption of oral penicillins.

3.9 Administration routes and dosage

In drinking water use.

Chickens:
The recommended dosage is 15 mg amoxicillin trihydrate per kg bodyweight per day, equivalent to 13.1 mg of amoxicillin/kg of bodyweight/day (corresponding to 18.8 mg veterinary medicinal product/kg bodyweight/day).
The total period of treatment should be for 3 days or in severe cases for 5 days.

Ducks:
Recommended dosage is 20 mg amoxicillin trihydrate/kg bodyweight per day, equivalent to 17.4 mg of amoxicillin/kg of bodyweight/day (corresponding to 25 mg veterinary medicinal product/kg bodyweight/day) for 3 consecutive days.

Turkeys:
Recommended dosage is 15-20 mg amoxicillin trihydrate/kg bodyweight per day, equivalent to 13.1-17.4- mg of amoxicillin/kg of bodyweight/day (corresponding to 18.8-25 mg veterinary medicinal product/kg bodyweight/day) for 3 days or in severe cases for 5 days.

Pigs:
Recommended dosage is 20 mg amoxicillin trihydrate/kg bodyweight per day, equivalent to 17.4 mg of amoxicillin/kg of bodyweight/day (corresponding to 25 mg veterinary medicinal product/kg bodyweight/day), for up to 5 days.

Use in drinking water:
For the preparation of medicated water, the body weight of the animals to be treated and their actual daily water consumption should be taken into account. Consumption may vary depending on factors like species, age, state of health, breed and husbandry system (e.g. different temperature, different light regimes). In order to obtain the correct dosage, the concentration of amoxicillin has to be adjusted accordingly.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

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

To ensure a correct dosage, bodyweight should be determined as accurately as possible.
All animals to be treated should have sufficient access to the water supply system to ensure adequate consumption of the medicated drinking water.
In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being treated.
Prepare the solution with fresh potable water.
Complete dissolution of the veterinary medicinal product should be ensured by gently mixing the veterinary medicinal product until fully dissolved. The homogeneity of the medicated drinking water should be kept during the administration to animals.
The maximum solubility of the veterinary medicinal product in water is 8 g/L at 20°C and 3 g/L at 5°C. 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 flow rate settings of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated.
Any medicated water which is not consumed within 24 hours should be discarded and the medicated drinking water replenished.

Use in liquid feed (for pigs):

Administer in the liquid feed, to give 20 mg amoxicillin trihydrate/kg bodyweight per day, equivalent to 17.4 mg of amoxicillin/kg of bodyweight/day (corresponding to 25 mg veterinary medicinal product/kg bodyweight/day) for up to 5 days. Medicated feed should be freshly prepared on at least 2 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 feeds lots prepared in the day.
Medicated liquid feed should be prepared with fresh potable water. Dissolve the required amount of veterinary medicinal product to some or all of the water needed to make the liquid feed. Maximum solubility of the veterinary medicinal product in water is approximately 8 g/L at 20°C and 3 g/L at 5°C. The complete dissolution of the powder should be ensured.
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 within 2 hours. Stability of amoxicillin in all commercial feeds has not been established. In order to ensure that any loss of amoxicillin activity is minimised, the quantity of medicated liquid feed prepared should not exceed the amount of feed which will be consumed within 2 hours. The medicated liquid feed should not be fermented. Any medicated liquid feed which is not consumed within 2 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.

After the end of the medication period, the water and liquid feed supply systems should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

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

No problems with overdosing 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 period(s)

Chickens (meat & offal): 1 day
Ducks (meat & offal): 9 days
Turkeys (meat & offal): 5 days
Pigs (meat & offal): 2 days

Not authorised for use in laying birds producing eggs for human consumption. Do not use within 4 weeks of the start of the laying period.

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 lipopolysaccharide 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)).

4.2 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

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 first opening the immediate packaging: 6 months
Shelf life after dissolution in drinking water according to directions: 24 hours
Shelf life after incorporation into liquid feed according to directions: 2 hours

5.3 Special precautions for storage

Do not refrigerate or freeze.
Store in the original container in order to protect from light.
Keep the container tightly closed.
Store in a dry place.

5.4 Nature and composition of immediate packaging

100 g jar made of high density polyethylene closed with a seal made of low density polyethylene/ polyethylene terephthalate/aluminium and a screw cap made of polypropylene.
Thermo-sealed 100 g bag made of low density polyethylene/aluminium/polyethylene terephthalate.
Zipped 500 g bag made of low density polyethylene/aluminium/polyethylene terephthalate.
Zipped 1 kg bag made of low density polyethylene/aluminium/polyethylene terephthalate.

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

Huvepharma NV

7. MARKETING AUTHORISATION NUMBER

Vm 30282/3007

8. DATE OF FIRST AUTHORISATION

20 April 2021

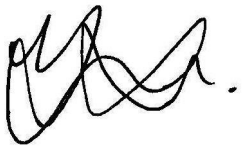
9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

May 2024

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).



Approved: 11 May 2024