1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MOXAPULVIS 500 mg/g powder for use in drinking water

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Amoxicillin trihydrate 574 mg (equivalent to Amoxicillin 500 mg)

Excipients:

Qualitative composition of excipients and other constituents
Silica, colloidal anhydrous
Sodium carbonate monohydrate
Lactose monohydrate

Homogeneous, fine, white to creamy-white powder.

3. CLINICAL INFORMATION

3.1 Target species

Chickens, ducks, turkeys, pigs

3.2 Indications for use for each target species

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

Pigs: For the treatment of pasteurellosis caused by *Pasteurella multocida* susceptible to amoxicillin and for the treatment of infections caused by *Streptococcus suis*.

3.3 Contraindications

Do not use in rabbits, hamsters, gerbils and guinea pigs or any other small herbivores.
Do not use in cases of hypersensitivity to penicillin or other substances of the beta-lactam group or to any of the excipients.

3.4 Special warnings

Pigs: The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of water, animals should be treated parenterally.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not effective against beta-lactamase producing organisms. Use of the product should be in accordance with official, national and regional antimicrobial policies.

Use of the product should be based on identification and 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 product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to 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 veterinary medicinal product if you know you are sensitised, or if you have been advised not to work with such preparations.

Handle this veterinary medicinal 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 immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Avoid inhalation of dust. Personal protective equipment consisting of disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143 and gloves should be worn when handling the veterinary medicinal product.

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

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 available data):	Allergic reactions*, hypersensitivity

*they may occasionally be serious

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:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic 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

Amoxicillin exerts its bactericidal action by inhibition of bacterial cell wall synthesis during multiplication. It is therefore in principle not compatible with bacteriostatic antibiotics (e.g. tetracyclines, macrolides and sulphonamides) which inhibit multiplication.

Synergism occurs with ß-lactam antibiotics and aminoglycosides.

3.9 Administration routes and dosage

In drinking water 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. To ensure a correct dosage, bodyweight should be determined as accurately as possible. The intake of medicated water depends on the clinical condition of the animal. In order to obtain the correct dosage, the concentration of amoxicillin may need to be adjusted accordingly. The use of suitably calibrated measuring equipment is recommended.

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:

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

The maximum solubility of the veterinary medicinal product is 65 g/L. At this concentration small particles and slight opalescence might be present due to calcium carbonate precipitation. 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 (equivalent to 13.1 mg amoxicillin) per kg bodyweight per day (corresponding to 27 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 (equivalent to 17.4 mg amoxicillin)/kg bodyweight per day (corresponding to 35 mg veterinary medicinal product/kg bodyweight/day) for 3 consecutive days.

Turkeys:
Recommended dosage is 15-20 mg amoxicillin trihydrate (equivalent to 13.1 - 17.4 mg amoxicillin)/kg bodyweight per day (corresponding to 27-35 mg veterinary medicinal product/kg bodyweight/day) for 3 days or in severe cases for 5 days.

Pigs:
For the treatment of pasteurellosis: Administer in the drinking water to give 20 mg amoxicillin trihydrate (equivalent to 17.4 mg amoxicillin)/kg bodyweight (corresponding to 35 mg veterinary medicinal product/kg bodyweight) daily.
The dose should be divided and administered at approximately 12 hourly intervals for up to 5 days.

For the treatment of infections caused by *Streptococcus suis*: Administer in the drinking water to give 20 mg amoxicillin trihydrate (equivalent to 17.4 mg amoxicillin)/ kg bodyweight (corresponding to 35 mg veterinary medicinal product/kg bodyweight) daily for 4 days.

No information regarding the compatibility of the veterinary medicinal product with biocides or feed additives in drinking water is available.

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

In case of overdosing the treatment should be symptomatic. 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

Chickens (meat and offal): 1 day
Ducks (meat and offal): 9 days
Turkeys (meat and offal):5 days
Pigs (meat and offal): 2 days
Not for use in birds producing or intended to produce eggs for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01CA04.

4.2 Pharmacodynamics

Amoxicillin is a time-dependent bactericidal antibiotic belonging to the semisynthetic penicillin group which acts by inhibiting the synthesis of bacterial cell walls during bacterial replication. It has a broad spectrum of activity against Gram positive and Gram negative bacteria, and owes its activity to the inhibition of the development of the peptidoglycan network structure in the bacterial cell wall.
There are three main mechanisms of resistance to beta-lactams: beta-lactamase production, production 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. Observed resistance rates are variable.

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

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

5.2 Shelf life

Bag:
Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 3 months.
Shelf life after reconstitution according to directions: 24 hours.

Jar:
Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 3 months.
Shelf life after reconstitution according to directions: 24 hours.

5.3 Special precautions for storage

Bag:
This veterinary medicinal product does not require any special storage conditions.

Jar:
Store below 25 °C.

5.4 Nature and composition of immediate packaging

Multi-layer laminated bag (Polyester/aluminium foil/polyethylene). Round, white HDPE jars that are closed by a polypropylene lid with a cardboard/aluminium/PE inner-layer.

Pack size: 1 kg bag, 100 g jar, 1 kg jar

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

V.M.D. n.v

7. MARKETING AUTHORISATION NUMBER(S)

VPA10817/003/001

8. DATE OF FIRST AUTHORISATION

16/03/2018

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

04/07/2025

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).