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:
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for use in drinking water
Homogeneous, fine, white to creamy-white powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens, ducks, turkeys, 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 use in rabbits, hamsters, gerbils and guinea pigs, or to birds producing eggs intended for human consumption.
Not effective against beta-lactamase producing organisms.
Do not use in known cases of hypersensitivity to penicillin or other substances of the beta-lactam group or to any of the excipients.

4.4 Special warnings for each target species

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.

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.

1. Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
3. 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.
- Wash any exposed skin after handling the product or medicated water.
- Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Penicillins and cephalosporins may cause hypersensitivity following administration. Allergic reactions to these substances may occasionally be serious.

4.7 Use during pregnancy, lactation or lay

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.

4.8 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.

4.9 Amounts to be administered and administration route

For use 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.

The following formula may be used to calculate the required concentration of product (in milligrams of product per litre of drinking water):

$$\frac{x \text{ mg product per kg bodyweight per day} \times \text{mean bodyweight (kg) of animals to be treated}}{\text{mean daily water consumption (l) per animal}} = x \text{ mg product per litre drinking water}$$

The maximum solubility of the product is 65 g/L.
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.

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 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 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 product/kg bodyweight/day) for 3 days or in severe cases for 5 days.

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

The calculated dose should be measured out with calibrated scales.

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

In case of overdosing the treatment should be symptomatic. No specific antidote is available.

4.11 Withdrawal period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibacterials for systemic use.
ATC vet code: QJ01CA04.

5.1 Pharmacodynamic properties

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.

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

Silica, colloidal anhydrous
Sodium carbonate monohydrate
Lactose monohydrate

6.2 Major incompatibilities

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

6.3 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.

6.4 Special precautions for storage

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

Jar:
Store below 25 °C.

6.5 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.

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 product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

V.M.D. n.v/s.a.
Hoge Mauw 900
2370 Arendonk
Belgium

8 MARKETING AUTHORISATION NUMBER(S)

VPA10817/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th March 2018

10 DATE OF REVISION OF THE TEXT