

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
All info of the outer package will appear on the immediate packaging label
(bag)
No outer package

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MOXAPULVIS 500 mg/g powder for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains: Amoxicillin trihydrate 574 mg (equivalent to Amoxicillin 500 mg)

3. PACKAGE SIZE

1 kg

4. TARGET SPECIES



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For use in drinking water

7. WITHDRAWAL PERIODS

Withdrawal period:

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 authorised for use in birds producing or intended to produce eggs for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 3 months.
Once reconstituted, use within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

V.M.D. n.v.

14. MARKETING AUTHORISATION NUMBERS

Vm 19968/3001

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
All info of the outer package will appear on the immediate packaging label (jar)
No outer package

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MOXAPULVIS 500 mg/g powder for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

Amoxicillin trihydrate 574 mg (equivalent to Amoxicillin 500 mg)

3. PACKAGE SIZE

100 g

1 kg

4. TARGET SPECIES



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For use in drinking water

7. WITHDRAWAL PERIODS

Withdrawal period:

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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 3 months.

Once reconstituted, use within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

V.M.D. n.v.

14. MARKETING AUTHORISATION NUMBERS

Vm 19968/3001

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

MOXAPULVIS 500 mg/g powder for use in drinking water

2. Composition

Each gram contains:

Active substance:

Amoxicillin trihydrate 574 mg
(equivalent to Amoxicillin 500 mg)

Homogeneous, fine, white to creamy-white powder.

3. Target species



Chickens, ducks, turkeys, and pigs.

4. Indications for use

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*.

5. 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.

6. Special warnings

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.

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 package leaflet 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 sensitized, 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.

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.

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.

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 β -lactam antibiotics and aminoglycosides.

Overdose:

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

Major incompatibilities:

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

7. 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 product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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:

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

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.

9. Advice on correct administration

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

Use of the veterinary medicinal product should be based on susceptibility testing and take into account official and local antimicrobial policies.

10. 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.

11. Special storage precautions

Keep out of the sight and reach of children.

Bag:

This veterinary medicinal product does not require any special storage conditions. Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month. Shelf life after first opening the container: 3 months. Shelf life after reconstitution according to directions: 24 hours.

Jar:

Store below 25 °C. Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month. Shelf life after first opening the container: 3 months. Shelf life after reconstitution according to directions: 24 hours.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 19968/3001

Bag of 1 kg.
Jars of 100g and 1 kg.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

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2370 Arendonk
Belgium

Gavin Hall
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