ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

{bag}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MOXAPULVIS 500 mg/g powder for use in drinking water
Amoxicillin

2. STATEMENT OF ACTIVE SUBSTANCES

Amoxicillin Trihydrate 574 mg/g equiv. with amoxicillin 500 mg/g

3. PHARMACEUTICAL FORM

Powder for use in drinking water

4. PACKAGE SIZE

1 kg

5. TARGET SPECIES

Chickens, ducks, turkeys, pigs.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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 birds producing or intended to produce eggs for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 3 months.
Once reconstituted, use within 24 hours.

For Poland only:
Termin ważności (EXP)
Once opened, use within 3 months.
Once reconstituted, use within 24 hours.

11. SPECIAL STORAGE CONDITIONS

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.

For Poland only:
Wyłącznie dla zwierząt
Wydawany z przepisu lekarza – Rp.
Do podawania pod nadzorem lekarza weterynarii.

For Italy only:
<Da vendersi soltanto dietro presentazione di ricetta medico veterinaria in triplice copia non ripetibile.>

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 19968/5002

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

Only for Italy:
Barcode within a box

Only for Poland:
Nr serii (Lot)

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

{jar}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MOXAPULVIS 500 mg/g powder for use in drinking water
Amoxicillin

2. STATEMENT OF ACTIVE SUBSTANCES

Amoxicillin Trihydrate 574 mg/g equiv. with amoxicillin 500 mg/g

3. PHARMACEUTICAL FORM

Powder for use in drinking water

4. PACKAGE SIZE

100 g
1 kg

5. TARGET SPECIES

Chickens, ducks, turkeys, pigs.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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 birds producing or intended to produce eggs for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 3 months.
Once reconstituted, use within 24 hours.

For Poland only:
Termin ważności (EXP)
Once opened, use within 3 months.
Once reconstituted, use within 24 hours.

11. SPECIAL STORAGE CONDITIONS

Store below 25 °C.

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.

For Poland only:
Wyłącznie dla zwierząt
Wydawany z przepisu lekarza – Rp.
Do podawania pod nadzorem lekarza weterynarii.

For Italy only:
<Da vendersi soltanto dietro presentazione di ricetta medico veterinaria in triplice copia non ripetibile.>

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 19968/5002

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

Only for Italy:
Barcode within a box

Only for Poland:
Nr serii (Lot)

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
MOXAPULVIS 500 mg/g powder for use in drinking water

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

Marketing authorisation holder and manufacturer responsible for batch release:
V.M.D. n.v.
Hoge Mauw 900
2370 Arendonk
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MOXAPULVIS 500 mg/g powder for use in drinking water
Amoxicillin

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

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

Homogeneous, fine, white to creamy-white powder.

4. INDICATION(S)

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.

5. 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.

6. ADVERSE REACTIONS

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

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.

Alternatively you can report via your national reporting system which can be found on the website of the
Belgium: Federal agency for medicines and health products - www.fagg-afmps.be/en/
Bulgaria: National Veterinary Service - www.nvms.government.bg
Croatia: Ministry of Agriculture, Veterinary and food safety directorate - www.veterinarstvo.hr
Estonia: State Agency of Medicines - www.ravimiamet.ee
France: ANMV – Agence Nationale du Médicament Vétérinaire, Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail - www.anses.fr
Greece: National Organization for Medicines - www.eof.gr
Hungary: National Food Chain Safety Office, Directorate of Veterinary Medicinal Products - http://www.nebih.gov.hu/en/specialities/veterinary
Ireland: Health Products Regulatory Authority (HPRA) - www.hpra.ie
Italy: Ministero della Salute, Direzione Generale della Sanità Animale e dei Farmaci veterinari, Uff. 4 - www.ministerosalute.it/
Latvia: Food and Veterinary Service - www.pvd.gov.lv
Lithuania: National Food and Veterinary Risk Assessment Institute - www.nmvrvi.lt
Luxembourg: Ministry of Health - www.ms.etat.lu
Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products - www.urpl.gov.pl
Portugal: Food and Veterinary Directorate General - www.dgav.pt
Romania: Institute for Control of biological products and veterinary medicines - www.icbmv.ro/
Spain: Spanish Agency of Medicines and Medical Devices - www.aemps.gob.es
The Netherlands: Medicines Evaluation Board - www.cbg-meb.nl
UK: Veterinary Medicines Directorate - vmd.defra.gov.uk

7. TARGET SPECIES

Chickens, ducks, turkeys, pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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):

***x** mg product per kg bodyweight per day*	*X*	*mean bodyweight (kg) of animals to be treated*	*= **x** mg product per litre drinking water*
mean daily water consumption (l) per animal			

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

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

10. 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 birds producing or intended to produce eggs for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Bag:
This veterinary medicinal product does not require any special storage conditions.
Keep out of the sight and reach of children.
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.
Keep out of the sight and reach of children.
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 WARNING(S)

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.

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

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 and evidence of teratogenic, foetotoxic or maternotoxic effets.
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 ß-lactam antibiotics and aminoglycosides.

Overdose (symptoms, emergency procedures, antidotes):
In case of overdosing the treatment should be symptomatic. No specific antidote is available.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal 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 or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

These measures should help to protect the environment.

Only for UK:
Medicines should not be disposed of via wastewater. Dispose of any unused product or waste materials in accordance with local requirements. Ask your veterinary surgeon how to dispose of medicines no longer required.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

XX

15. OTHER INFORMATION

Bag of 1 kg.
Jars of 100g and 1 kg.
Not all pack sizes may be marketed.
Marketing authorisation number:
For animal treatment only.
To be supplied only on veterinary prescription.

Only for Italy:
<Da vendersi soltanto dietro presentazione di ricetta medico veterinaria in triplice copia non ripetibile.>

Approved 25 April 2023