LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 g jar, 100 g sachet, 500 g bag and 1 kg bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram (g) contains:

Active substance:

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

3. PHARMACEUTICAL FORM

Powder for use in drinking water.

4. PACKAGE SIZE

100 g
500 g
1 kg

5. TARGET SPECIES

Chickens (broiler, pullet, breeder), turkeys (broiler, breeder), ducks (broiler, breeder) and pigs.

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In drinking water use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
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
Once opened used by…

11. SPECIAL STORAGE CONDITIONS

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

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.

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

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 30282/4046

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

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

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

Marketing authorisation holder

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium

Manufacturer responsible for batch release:

HUVEPHARMA SA
34 rue Jean Monnet
ZI d'Etriché
Segré
49500 Segré-en-Anjou Bleu
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

Each g (gram) contains:

Active substance:

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

Powder for use in drinking water
White to slightly yellow powder.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

Do not use in horses or to rabbits, guinea pigs, hamsters, gerbils or any 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 known hypersensitivity to penicillins or other β-lactam antibiotics or to any of the excipients.
Do not administer to animals with renal disease including anuria or oliguria.
Do not use in the presence of ß-lactamase-producing bacteria.

6. ADVERSE REACTIONS

Hypersensitivity reactions may occur, which can occasionally be serious, with the severity varying from skin rash to anaphylactic shock.
Gastrointestinal symptoms (vomiting, diarrhoea) may occur.
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 {national system details}

7. TARGET SPECIES

Chickens (broiler, pullet, breeder), turkeys (broiler, breeder), ducks (broiler, breeder) and pigs.

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

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 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 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 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 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.

The following formula may be used to calculate the required amount of veterinary medicinal product in mg per litre of drinking water:

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

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.
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 immediately before use.
Complete dissolution of the product should be ensured by gently mixing the product until fully dissolved. The homogeneity of the medicated drinking water should be kept during the administration to animals.
The maximum solubility of the 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 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 product to some or all the water needed to make the liquid feed. Maximum solubility of the 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 minimized, 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.
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.

9. ADVICE ON CORRECT ADMINISTRATION

Use in drinking water: In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being treated.

Use in liquid feed: 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.

10. WITHDRAWAL PERIODS

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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 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

12. SPECIAL WARNING(S)

Special warnings for each target species:
The product is not effective against beta-lactamase producing organisms.
Complete cross-resistance has been shown between amoxicillin and other penicillins, in particular amino-penicillins. Use of the product/amoxicillin should be carefully considered when antimicrobial 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 product prescribed by the veterinarian.

Special precautions for use in animals:
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 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 amoxicillin and may decrease the effectiveness of treatment with other penicillins, due to the potential for cross-resistance.

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 product.
Handle this 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 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 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.

Pregnancy, lactation and lay:
Laboratory studies in rats have not produced any evidence of a teratogenic effect due to the administration of amoxicillin.
Use only according to the benefit/risk assessment of the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
The 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.

Overdose (symptoms, emergency procedures, antidotes):
No problems with overdosage have been reported. Treatment should be symptomatic and 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.

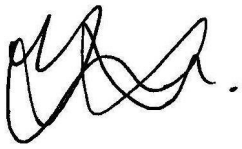
13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Not all pack sizes may be marketed.



Approved: 20 April 2021