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 VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram (g) contains:

Active substance:

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

3. PACKAGE SIZE

100 g
500 g
1 kg

4. TARGET SPECIES

Chickens (broiler, pullet, for reproduction), turkeys (broiler, for reproduction), ducks (broiler, for reproduction) and pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

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.

8. 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…

9. SPECIAL STORAGE PRECAUTIONS

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

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 THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

14. MARKETING AUTHORISATION NUMBERS

Vm 30282/3007

15. 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 of the veterinary medicinal product

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

2. Composition

Each g (gram) contains:

Active substance:

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

White to slightly yellow powder.

3. Target species

Chickens (broiler, pullet, for production), turkeys (broiler, for production), ducks (broiler, for production) and pigs.

4. Indications for use

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, 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 hypersensitivity to penicillins or other β-lactam antibiotics or to any of the excipients.
Do not use in animals with renal disease including anuria or oliguria.
Do not use in the presence of ß-lactamase-producing bacteria.

6. Special warnings

Special warnings:
The veterinary medicinal product is not effective against beta-lactamase producing organisms.

Cross-resistance has been shown between amoxicillin and other penicillins, in particular amino-penicillins in bacteria susceptible to amoxicillin. Use of the veterinary medicinal product/amoxicillin should be carefully considered when 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 veterinary medicinal product prescribed by the veterinarian.

Special precautions for safe use in the target species:
Use of the veterinary medicinal product should be based on 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 veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies. Use of the veterinary medicinal 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.
Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.
The antimicrobial should not be used as part of heard health programmes.
Not for use for prophylaxis.

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 veterinary medicinal product.
Handle this veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 shown any evidence of teratogenic effects.

Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other veterinary medicinal products and other forms of interaction:
The veterinary medicinal 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:
No problems with overdosaging have been reported. Treatment should be symptomatic and 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 the available data)	Hypersensitivity reaction (varying from allergic skin reaction to anaphylactic shock (severe allergic reaction)) Digestive tract disorders (vomiting, diarrhoea)

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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: {national system details}.

8. Dosage for each species, routes 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 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/kg bodyweight per day, equivalent to 17.4 mg of amoxicillin/kg of bodyweight/day (corresponding to 25 mg veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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.

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:

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

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

100 g jar made of high density polyethylene closed with a seal made of low density polyethylene/ polyethylene terephthalate/aluminium and a screw cap made of polypropylene.
Thermo-sealed 100 g bag made of low density polyethylene/aluminium/polyethylene terephthalate.
Zipped 500 g bag made of low density polyethylene/aluminium/polyethylene terephthalate.
Zipped 1 kg bag made of low density polyethylene/aluminium/polyethylene terephthalate.

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.

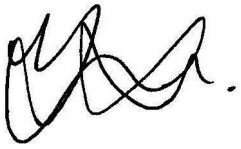
16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
HUVEPHARMA NV
Uitbreidingstraat 80
2600 Antwerp
Belgium
+32 3 292 83 05 or +32 3 288 18 49
pharmacovigilance@huvepharma.com

Manufacturer responsible for batch release:
HUVEPHARMA SA
34 rue Jean Monnet
ZI d'Etriché
Segré
49500 Segré-en-Anjou Bleu
France

Local representative and contact details to report suspected adverse reactions:

17. Other information



Approved: 11 May 2024