LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE/OUTER PACKAGE

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Huvacillin 800 mg/g Powder for use in drinking water.

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram (g) contains:
Amoxicillin ……697 mg
(equivalent to 800 mg of amoxicillin trihydrate).

3. PACKAGE SIZE

100 g
500 g
1 kg

4. TARGET SPECIES

Chickens (for reproduction, broiler, pullet), pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use (for chickens and pigs)

7. WITHDRAWAL PERIODS

Withdrawal periods:
Chickens: Meat and offal: 1 day.
Pigs: Meat and offal: 2 days.
Not for use in birds producing or intended to produce eggs for human consumption.

8. EXPIRY DATE

Exp.
Once opened use within 6 months
Once dissolved in drinking water use within 24 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 and moisture.
Keep the original container tightly closed in order to protect from moisture.
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 OF THE MARKETING AUTHORISATION HOLDER

HUVEPHARMA NV

14. MARKETING AUTHORISATION NUMBERS

Vm 30282/3000

15. BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal veterinary medicinal product

Huvacillin 800 mg/g Powder for use in drinking water for chickens and pigs

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 (for reproduction, broiler, pullet) and pigs.

4. Indications for use

In chickens:
Treatment of respiratory tract and gastrointestinal infections.

In pigs:
Treatment of respiratory tract, gastrointestinal and urogenital infections, infections secondary to viral diseases and septicaemia.

5. Contraindications

Do not use in horses, in rabbits, guinea pigs, hamsters, gerbils or any other small herbivores 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 ß-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, as the veterinary medicinal is not effective against them.

6. Special warnings

Special warnings:
The uptake of medication by animals may be altered as a consequence of illness. In case of insufficient water/feed uptake, animals should be treated parenterally instead using a suitable injectable veterinary medicinal prescribed by the veterinarian.
Cross-resistance has been shown between amoxicillin and other penicillins, in particular amino-penicillins, in bacteria susceptible to amoxcillin. Use of the veterinary medicinal /amoxicillin should be carefully considered when antimicrobial susceptibility testing has shown resistance to penicillins because its effectiveness may be reduced.

Special precautions for safe use in the target species:
Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogens. 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 package leaflet 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 antibacterial 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.
Do not leave medicated water available to other animals.
Repeated and protracted use should be avoided by improving management practices through cleaning and disinfection.
Prolonged use of the veterinary medicinal product can induce intestinal bacterial flora alteration and favour the development of non-sensitive microorganisms.
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.
This veterinary medicinal product may be irritating to the respiratory tract.
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 when handling the veterinary medicinal product or the medicated water.
Wash hands after use. Wash any exposed skin after handling the veterinary medicinal product or medicated water.
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 productIn 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:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Use only according to the benefit/risk assessment by the responsible veterinarian.
Laboratory studies in rats have not shown any evidence of teratogenic effects.

Interaction with other medicinal products and other forms of interaction:
Do not combine with bacteriostatic antibiotics.
Synergism with other beta-lactam antibiotics and aminoglycosides may occur.
Do not use simultaneously with neomycin since it blocks the absorption of oral penicillins.
Do not use together with antibiotics which inhibit bacterial protein synthesis as they can antagonise the bactericidal effect of penicillins.

Overdose:
No other adverse eventss are known than those mentioned in section “Adverse events”.
Amoxicillin has a wide margin of safety. 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 (for reproduction, broiler, pullet), pigs

Undetermined frequency (cannot be estimated from the available data)’	Hypersensitivity reaction (varying from allergic skin reaction to anaphylactic shock (severe allergic reaction))[1] Digestive tract disorders (vomiting, diarrhoea)

[1]Immediately stop administering the veterinary medicinal product.

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 of administration

In drinking water use, for chickens and pigs.

Chickens:
The recommended dosage is 23.0 mg amoxicillin trihydrate per kg bodyweight per day, equivalent to 20 mg of amoxicillin/kg of bodyweight/day (corresponding to 28.8 mg veterinary medicinal product/kg bodyweight/day) for 3 to 5 consecutive days.

Pigs:
The recommended dosage is 12.9 mg amoxicillin trihydrate per kg bodyweight, i.e. 11.2 mg amoxicillin/bodyweight/day, (corresponding to 16.1 mg veterinary medicinal product/kg bodyweight/day) for 3 to 5 consecutive days.

9. Advice on correct administration

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:

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

To ensure a correct dosage, bodyweight should be determined as accurately as possible.
The required amount of veterinary medicinal product should be weighed as accurately as possible using suitability calibrated weighing equipment.
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.
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. Any unused medicated water should be discarded after 24 hours and the medicated drinking water replenished.
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,
When using a water tank, it is recommended to prepare a stock solution and to dilute it to the target final concentration. Turn off the water supply to the tank until all the medicated solution is consumed.
For stock solutions, take care not to exceed the maximum solubility of the veterinary medicinal product, i.e. 3 g/L in soft/hard water at 5°C or 8g/L at 20°C.
When using a proportioner, adjust flow rate settings of the dosing pump according to the concentration of the stock solution and water intake of the animals to be treated.
Care should be taken that the intended dose will be completely ingested.

10. Withdrawal periods

Chickens: Meat and offal: 1 day;
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.
Do not refrigerate or freeze.
Store in the original container in order to protect from light and moisture
Keep the container tightly closed in order to protect from moisture.
Store in a dry place.

Do not use this veterinary medicinal 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

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

Vm 30282/3000

100 g jar
100 g bag
500 g bag
1 kg bag

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

August 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

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 28 April 2024