

[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trioxyl 500 mg/g powder for use in drinking water for chickens, turkeys, ducks and pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substances:

Amoxicillin (equivalent to 500 mg amoxicillin trihydrate) 436 mg

Excipients:

Qualitative composition of excipients and other constituents
Anhydrous citric acid

A white powder. Clear and colourless liquid when in solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens, turkeys, ducks and pigs.

3.2 Indications for use for each target species

Chickens, turkeys and ducks: For the treatment of infections caused by bacteria susceptible to amoxicillin.

Pigs: For the treatment of pasteurellosis.

3.3 Contraindications

This veterinary medicinal product should not be administered to rabbits, guinea pigs, hamsters, gerbils or any other small herbivore.

Do not use in cases of hypersensitivity to the active substance, to penicillins, to β -lactam antibiotics, or to any of the excipients.

Do not administer to animals with renal disease including anuria or oliguria.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not effective against beta-lactamase producing organisms.

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

Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Use of the veterinary medicinal 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 veterinary medicinal 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.

People with known hypersensitivity the active substance should avoid contact with the veterinary medicinal product.

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.

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.

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product .

Wash any exposed skin after handling the veterinary medicinal product or medicated water or feed. Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens, turkeys, ducks and pigs:

Undetermined frequency (cannot be estimated from the available data):	Hypersensitivity reaction
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¹ May occasionally be serious.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the immediate packaging for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Laboratory studies in rats have not produced any evidence of teratogenic effects.

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

Laying birds:

Do not use in birds producing eggs for human consumption or within 3 weeks of onset of laying.

3.8 Interaction with other 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.

3.9 Administration routes and dosage

In drinking water use.

Prepare the solution with fresh potable water immediately before use. Any medicated water which is not consumed within 12 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 veterinary medicinal product per litre of drinking water):

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

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 animals. In order to obtain the correct dosage, the concentration of amoxicillin may need to be adjusted accordingly.

Chickens

The recommended dosage is 15 mg amoxicillin trihydrate per kg bodyweight per day (corresponding to 30 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 (corresponding to 40 mg veterinary medicinal product/kg bodyweight/day) for 3 consecutive days.

Turkeys

Recommended dosage is 15-20 mg amoxicillin trihydrate/kg bodyweight per day (corresponding to 30-40 mg veterinary medicinal 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/kg bodyweight (corresponding to 40 mg veterinary medicinal product/kg bodyweight) daily for up to 5 days.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No problems with overdosage have been reported. Treatment should be symptomatic and no specific antidote is available.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Meat and offal:

Chickens	1 day.
Ducks	9 days.
Turkeys	5 days.
Pigs	2 days.

Not for use in birds producing eggs for human consumption, and within 3 weeks of onset of laying.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QJ01CA04

4.2 Pharmacodynamics

Amoxicillin is a bactericidal antibiotic belonging to the group of semisynthetic penicillins with a broad spectrum of activity against Gram-positive and Gram-negative bacteria. It owes its activity to the inhibition of the development of the peptidoglycan network structure in the bacterial cell wall.

4.3 Pharmacokinetics

Amoxicillin is well absorbed following oral administration and it is stable in the presence of gastric acids. Excretion of amoxicillin is mainly in the unchanged form via the kidneys to give high concentration in renal tissue and urine. Amoxicillin is well distributed in body fluids.

Studies in birds have indicated that amoxicillin is distributed and eliminated more rapidly than in mammals.

Biotransformation appeared a more important route of elimination in birds than in mammals.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 21 months.

Shelf life after first opening the immediate packaging: 3 months.

Shelf life after dilution or reconstitution according to directions: 12 hours.

5.3 Special precautions for storage

Do not store above 30 °C.

Keep the bags tightly closed.

5.4 Nature and composition of immediate packaging

Thermosealed bags made of polyester, aluminium and polyethylene complex.

Pack sizes:

400 g bag

1 kg bag

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Univet Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10990/048/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 27/01/2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

19/02/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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