SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solamocta 697 mg/g powder for use in drinking water for chickens, ducks and turkeys

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:

Amoxicillin	697 mg
equivalent to amoxicillin trihydrate	800 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium carbonate monohydrate
Sodium citrate
Silica colloidal anhydrous

White to pale yellow-white powder.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (broilers, pullets, breeders), ducks (broilers, breeders), turkeys.

3.2 Indications for use for each target species

Treatment of infections in chickens, turkeys and ducks caused by bacteria susceptible to amoxicillin.

3.3 Contraindications

Do not use in the presence of ß-lactamase-producing bacteria.
Do not use in rabbits, guinea pigs, hamsters, gerbils or any other small herbivores.
Do not use in cases of hypersensitivity to penicillins or other substances from the beta-lactam group or to any of the excipients.
Do not use in ruminants or horses.

3.4 Special warnings

None.

3.5 Special precautions for use

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 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 bacterial resistance to amoxicillin and may decrease its effectiveness.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Avoid inhalation of dust.
Personal protective equipment consisting of disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143 should be worn when handling the veterinary medicinal product.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact, which may occasionally be serious. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. In case of contact with eyes or skin, wash immediately with water. Do not handle this veterinary medicinal product if you know you are sensitized or if you have been advised not to work with such preparations. 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 and show the physician this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention. Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Chickens, ducks, turkeys:

Undetermined frequency (cannot be estimated from the available data)	Hypersensitivity reaction*

* 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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Use only according to the benefit-risk assessment by the responsible veterinarian.
Laboratory studies in rats have not produced any evidence of teratogenic effects.

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 and sulphonamides.
Synergism occurs with ß-lactam antibiotics and aminoglycosides.

3.9 Administration routes and dosage

In drinking water use.

Chickens
The recommended dosage is 13.1 mg amoxicillin (equivalent to 18.8 mg veterinary medicinal product) per kg body weight daily for 3 consecutive days or in severe cases for 5 consecutive days.

Ducks
Recommended dosage is 17.4 mg amoxicillin (equivalent to 25 mg veterinary medicinal product) per kg body weight daily for 3 consecutive days.

Turkeys
Recommended dosage is 13.1-17.4 mg amoxicillin (equivalent to 18.8 to 25 mg veterinary medicinal product) per kg body weight daily for 3 consecutive days or in severe cases for 5 consecutive days.

Prepare the solution with fresh tap water immediately before use. Any unused medicated water should be discarded after 12 hours. In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being treated. 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:

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

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

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. 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.

Maximum solubility of the veterinary medicinal product in water of at least 10 °C is approximately 6 g/l within 10 minutes. At lower temperatures (4 °C), the maximum solubility is approximately 5 g/l within 10 minutes.
The use of suitably calibrated measuring equipment is recommended.
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.

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

None known.

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

Chickens (meat and offal): 1 day
Ducks (meat and offal): 9 days
Turkeys (meat and offal): 5 days

Do not use within 3 weeks before the start of the laying period.
Not for use in birds producing eggs for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01CA04.

4.2 Pharmacodynamics

Amoxicillin is a time-dependent bactericidal antibiotic which acts by inhibiting the synthesis of bacterial cell walls during bacterial replication. It inhibits the formation of bridges between the chains of linear polymers constituting the peptidoglycan cell wall of Gram-positive bacteria.

Amoxicillin is a broad-spectrum penicillin. It is also active against a limited range of Gram-negative bacteria on which the outer layer of the bacterial cell wall is composed of lipopolysaccharides and proteins.

There are three main mechanisms of resistance to beta-lactams: beta-lactamase production, altered expression and/or modification of penicillin binding proteins (PBP), and decreased penetration of the outer membrane. One of the most important is the inactivation of penicillin by beta-lactamase enzymes produced by certain bacteria. These enzymes are capable of cleaving the beta-lactam ring of penicillins, making them inactive. The beta-lactamase could be encoded in chromosomal or plasmidic genes.

Cross-resistance is observed between amoxicillin and other penicillins, particularly with aminopenicillins.

The use of extended spectrum beta-lactam drugs (e.g. aminopenicillins) might lead to the selection of multi-resistant bacterial phenotypes (e.g. those producing extended spectrum beta-lactamases (ESBLs)).

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: 3 years.
Shelf life after first opening the immediate packaging: 3 months.
Shelf life after dissolution according to directions: 12 hours.

5.3 Special precautions for storage

This unopened veterinary medicinal product does not require any special storage conditions.
Keep the bag tightly closed after first opening in order to protect from moisture.

5.4 Nature and composition of immediate packaging

Sachet with outside to inside layers of polyethylene terephthalate, polyethylene, aluminum, polyethylene (PET/PE/ALU/PE).

Sachet with outside to inside layers of polyethylene terephthalate, aluminum, polyamide, polyethylene (PET/ALU/PA/PE).

Pack sizes: 100 g, 250 g, 500 g and 1 kg.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Eurovet Animal Health B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 16849/4052

8. DATE OF FIRST AUTHORISATION

11 April 2016

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

January 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved 29 April 2025