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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for use in drinking water.
White to pale yellow-white powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Chicken (broiler, pullet, breeder), duck (broiler, breeder), turkey.

4.2 Indications for use, specifying the target species

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

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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 information about susceptibility of the target bacteria. Use of the 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.
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.

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 product if you know you are sensitised or if you have been advised not to work with such preparations. Handle this 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 doctor 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.

4.6 Adverse reactions (frequency and seriousness)

Penicillins and cephalosporins may cause hypersensitivity reactions which may occasionally be serious.

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats have not produced any evidence of a teratogenic effect due to the administration of amoxicillin. Use only accordingly the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interactions

The 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.

4.9 Amounts to be administered and administration route

For use in drinking water.

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. The following formula may be used to calculate the required concentration of product (in milligrams of product per litre drinking water):

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

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing. The uptake of medicated water depends on the clinical condition of the birds. In order to obtain the correct dosage the concentration of amoxicillin has to be adjusted taking into account water intake. 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 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 calculated dose should be measured out with calibrated scales.
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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

None known.

4.11 Withdrawal period(s)

Chickens (meat and offal): 1 day
Ducks (meat and offal): 9 days
Turkeys (meat and offal): 5 days
Not for use in birds producing or intended to produce eggs for human consumption. Do not use within 3 weeks of onset of laying.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Beta-lactam antibacterials, Penicillins with extended spectrum, amoxicillin
ATCvet code: QJ01CA04

5.1 Pharmacodynamic properties

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 lipolysaccharide 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)).

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium carbonate monohydrate
Sodium citrate
Silica colloidal anhydrous

6.2 Major incompatibilities

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

6.3 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 dilution or reconstitution according to directions 12 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

100 g, 250 g, 500 g and 1 kg sachet with outside to inside layers of polyethylene terephthalate, polyethylene, aluminum, polyethylene (PET/PE/ALU/PE).

100 g, 250 g, 500 g and 1 kg sachet with outside to inside layers of polyethylene terephthalate, aluminum, polyamide, polyethylene (PET/ALU/PA/PE).

Not all pack sizes may be marketed

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

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

7 MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA10989/064/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 2016
Date of last renewal: 10th July 2020

10 DATE OF REVISION OF THE TEXT

July 2020