

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
100 g sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solamocta 697 mg/g powder for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

Amoxicillin	697 mg
equivalent to amoxicillin trihydrate	800 mg

3. PACKAGE SIZE

100 g

4. TARGET SPECIES

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



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal period:

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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use by:
Once opened use within 3 months.
Once dissolved use within 12 hours.

9. SPECIAL STORAGE PRECAUTIONS

Keep the bag tightly closed after first opening in order to protect from moisture.

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

Eurovet Animal Health B.V.

14. MARKETING AUTHORISATION NUMBER

Vm 16849/4052

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:
100 g sachet

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each gram contains:

Active substance:

Amoxicillin	697 mg
Equivalent to amoxicillin trihydrate	800 mg

White to pale yellow-white powder.

3. Target species

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

4. Indications for use

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

5. Contraindications

Do not use in the presence of β -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.

6. Special warnings

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.

Laying birds:

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

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 β -lactam antibiotics and aminoglycosides.

Overdose:

None known.

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:

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

Reporting adverse events is important. It allows continuous safety monitoring of a 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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

Refer to section 'Dosage for each species, route and method of administration'.

10. 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.

11. Special storage precautions

Keep out of the sight and reach of children.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp.

The expiry date refers to the last day of that month.

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

Shelf life after dilution or reconstitution according to directions: 12 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 NUMBER AND PACK SIZES

Vm 16849/4052

Pack sizes: 100 g, 250 g, 500 g and 1 kg.

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 manufacturer responsible for batch release <and contact details to report suspected adverse reactions>:

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

Local representatives and contact details to report suspected adverse reactions:

Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel: +44 (0) 1939 211200

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet 100 g, 250 g, 500g, 1 kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each gram contains:

Active substance:

Amoxicillin	697 mg
Equivalent to amoxicillin trihydrate	800 mg

White to pale yellow-white powder.

3. PACKAGE SIZE

100 g
250 g
500 g
1 kg

4. TARGET SPECIES

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



5. INDICATIONS FOR USE

Indications for use

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

6. CONTRAINDICATIONS

Contraindications

Do not use in the presence of β -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.

7. SPECIAL WARNINGS

Special warnings

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.

Laying birds:

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

Interactions 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 β -lactam antibiotics and aminoglycosides.

Overdose:

None known.

Major incompatibilities:

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

8. ADVERSE EVENTS

Adverse events

Chickens, ducks, turkeys:

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, 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 on this label, or via your national reporting system at:

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e-mail: adverse.events@vmd.gov.uk

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

In drinking water use.

Chickens

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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.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

Refer to section 'Dosage for each species, route and method of administration'.

11. WITHDRAWAL PERIODS

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.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

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 or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Marketing authorisation number and pack sizes:

Vm 16849/4052

100 g, 250 g, 500 g and 1 kg

Not all pack sizes may be marketed.

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Contact details

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse reactions:

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

Local representatives and contact details to report suspected adverse reactions:

Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel: +44 (0) 1939 211200

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

18. OTHER INFORMATION

Other information

POM-V

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once opened use by:
Once opened use within 3 months.
Once dissolved use within 12 hours.

21. BATCH NUMBER

Lot {number}

Gavin Hall
Approved 29 April 2025