Labelling

SOLAMOCTA

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{TEAR OPEN LABEL, 100 g package}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SOLAMOCTA 697 mg/g powder for use in drinking water for chickens, ducks and turkeys
Amoxicillin (as trihydrate)

2. STATEMENT OF ACTIVE SUBSTANCE

Each gram contains:
Active substance:
Amoxicillin 697 mg
equivalent to amoxicillin trihydrate 800 mg

3. PHARMACEUTICAL FORM

Powder for use in drinking water

4. PACKAGE SIZE

100

5. TARGET SPECIES

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

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:
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.

9. SPECIAL WARNINGS, IF NECESSARY

User warnings: Penicillins and cephalosporins may occasionally cause severe allergic reactions. Read the package leaflet before use.

10. EXPIRY DATE

Shelf life after first opening the sachet: 3 months.
Shelf life after dilution or reconstitution according to directions: 12 hours
EXP {month/year}

Once opened use by:

11. SPECIAL STORAGE CONDITIONS

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.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 16849/4052

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

(Inside of tear off label, 100 g)

PACKAGE LEAFLET :
SOLAMOCTA 697 mg/g
powder for use in drinking water for chickens, ducks and turkeys

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Eurovet Animal Health B.V. Handelsweg 25, NL-5531 AE Bladel, The Netherlands

Manufacturer responsible for batch release:
Eurovet Animal Health B.V. Handelsweg 25, NL-5531 AE Bladel, The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

SOLAMOCTA 697 mg/g powder for use in drinking water for chickens, ducks and turkeys
Amoxicillin (as trihydrate)

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each gram contains:
Active substance:
Amoxicillin 697 mg
Equivalent to amoxicillin trihydrate 800 mg
White to pale yellow-white powder.

4. INDICATION

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

5. 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."

6. ADVERSE REACTIONS

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

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 inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

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

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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.

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 sachet: 3 months.
Shelf life after dilution or reconstitution according to directions: 12 hours

12. SPECIAL WARNINGS

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 package leaflet may increase the prevalence of bacteria 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.

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..

Interaction with other medicinal products and other forms of interaction: 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.

Overdose (symptoms, emergency procedures, antidotes): None known.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2020

15. OTHER INFORMATION

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

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

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET LEAFLET 100 g, 250 g, 500 g , 1 kg

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Marketing authorisation holder:
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Manufacturer responsible for batch release:
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Amoxicillin (as trihydrate)

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each gram contains:
Active substance:
Amoxicillin 697 mg
Equivalent to amoxicillin trihydrate 800 mg

White to pale yellow-white powder.

4. PHARMACEUTICAL FORM

Powder for use in drinking water

5. PACKAGE SIZE

100 g, 250 g, 500 g and 1 kg

6. INDICATION

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

7. 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.

8. ADVERSE REACTIONS

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

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}

9. TARGET SPECIES

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

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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11. ADVICE ON CORRECT ADMINISTRATION

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

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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.

Lay:
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Interaction with other medicinal products and other forms of interaction:
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Synergism occurs with ß-lactam antibiotics and aminoglycosides.

Overdose (symptoms, emergency procedures, antidotes):
None known.

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

15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

16. DATE ON WHICH THE LABEL WAS LAST APPROVED

July 2020

17. OTHER INFORMATION

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19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

20. EXPIRY DATE

EXP {month/year}
Once opened use by:

Shelf life after first opening the sachet: 3 months.
Shelf life after dilution or reconstitution according to directions: 12 hours.

21. MARKETING AUTHORISATION NUMBER(S)

Vm 16849/4052

22. MANUFACTURER'S BATCH NUMBER

Lot{number}

Approved 30 July 2020