PARTICULARS TO APPEAR ON THE OUTER PACKAGE { Outside of tear open leaflet / 1 LITRE BOTTLE / 5 LITRES CONTAINER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metaxol 20/100 mg/ml solution for use in drinking water.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substances:

Trimethoprim	20 mg
Sulfamethoxazole	100 mg

3. PACKAGE SIZE

1 litre, 5 litres

4. TARGET SPECIES

Pigs (fattening pigs) and chickens (broilers).

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Route of administration: in drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Pigs: Meat and offal: 8 days.
Chickens: Meat and offal: 5 days.
Not for use in birds producing or intended to produce eggs for human consumption.

8. EXPIRY DATE

Exp.: {mm/yyyy}
Once opened use within 1 year. Use by: __/__/__

Shelf life after dilution or reconstitution according to directions: 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

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 NUMBERS

Vm 16849/5008

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Pregnant women should take extra care when handling this product.
See full user warnings for details.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET: (Inside of the tear open leaflet / 1 Litre bottle / 5 Litres container)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metaxol 20/100 mg/ml solution for use in drinking water for pigs and chickens.

2. COMPOSITION

Each ml contains:

Active substances:
Trimethoprim 20 mg
Sulfamethoxazole 100 mg

Excipients:
N-methyl pyrrolidone 690,8 mg

Clear, pale yellow to brownish-yellow solution.

3. TARGET SPECIES

Pigs (fattening pigs) and chickens (broilers).

4. INDICATIONS FOR USE

Fattening pigs:
Treatment and metaphylaxis of:
- Post-weaning diarrhoea caused by beta-haemolytic K88-positive, K99-positive or 987P *Escherichia coli* strains susceptible to trimethoprim-sulfamethoxazole.
- Secondary bacterial infections caused by *Pasteurella multocida*, *Actinobacillus pleuropneumoniae*, *Streptococcus spp*. and *Haemophilus parasuis* susceptible to trimethoprim-sulfamethoxazole.

Broilers:
Treatment and metaphylaxis of
- Colibacillosis caused by *Escherichia coli* susceptible to trimethoprim-sulfamethoxazole.
- Coryza caused by *Avibacterium paragallinarum* susceptible to trimethoprim-sulfamethoxazole.

The presence of the disease in the group/flock must be established before the veterinary medicinal product is used.

5. CONTRAINDICATIONS

Do not use in animals suffering from severe liver or kidney disease, oliguria or anuria.
Do not use in animals with impaired haematopoietic systems.
Do not use in cases of hypersensitivity to sulphonamides or trimethoprim or any of the excipients.

6. SPECIAL WARNINGS

Special warnings for each target species:
Severely diseased animals can have a decreased appetite and water consumption. If necessary the concentration of the veterinary medicinal product in the drinking water should be adjusted to make sure that the recommended dosage is being consumed. However if the concentration of the veterinary medicinal product is increased too much, the intake of the medicated drinking water decreases for palatability reasons. Therefore water intake should be monitored regularly, especially in broilers.
In case of insufficient intake of water, pigs should be treated parenterally.

Special precautions for use in animals:
Due to the likely variability (time, geographical) in susceptibility of bacteria for potentiated sulphonamides, occurrence of resistance of bacteria may differ from country to country and even from farm to farm, and therefore bacteriological sampling and susceptibility testing are recommended. Use of the veterinary medicinal product should be based on culture and sensitivity of micro-organisms from diseased cases on farm or from recent previous experience on the farm. Use of the veterinary medicinal product deviating from the instructions may increase the prevalence of bacteria resistant to sulfamethoxazole and trimethoprim and may also decrease the effectiveness of combinations of trimethoprim with other sulphonamides due to the potential for cross resistance. Official and local antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Sulphonamides may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to sulphonamides may lead to cross reactions with other antibiotics. Allergic reactions to these substances may occasionally be serious. Do not handle this veterinary medicinal product if you know you are sensitive to sulphonamides.
If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the physician this warning.
Laboratory studies in rabbits and rats conducted with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.
This veterinary medicinal product may cause skin- and respiratory irritation as well as eye damage.
Impermeable gloves, e.g. rubber or latex and protective glasses, should be worn when handling the product including when mixing the product with drinking water. Avoid inhalation. In the event of eye contact, rinse the eye with large amounts of clean water and, if irritation occurs, seek medical attention. In the event of accidental ingestion, seek medical advice. Wash hands and contaminated skin immediately after handling the veterinary medicinal product.

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

Other precautions:
Not applicable.

Pregnancy, lactation or lay:
The safety of the veterinary medicinal product has not been established in pigs and chickens during pregnancy, lactation, lay or in animals intended for breeding.
Laboratory studies in rabbits and rats conducted with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Do not combined with other veterinary medicinal products.

Overdose:
In chickens an acute overdose will likely not occur because the birds will be reluctant to drink the strongly concentrated drinking water (too bitter taste if above 2 litres of the veterinary medicinal product per 1000 litres drinking water). Chronic overdose in chickens will result in a strongly diminished water- and feed intake and retarded growth.

Special restrictions for use and special conditions for use:
Not applicable.

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

7. ADVERSE EVENTS

Pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity.

Chickens:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity, decreased drinking.

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 the 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 {national system details}.

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

Route of administration: in drinking water use.
The veterinary medicinal product can be added directly to the drinking water to prepare a therapeutic solution at the calculated concentration, but can also be used in a concentrated stock solution by adding 200 ml of the veterinary medicinal product per litre of water and diluting this further.

Fattening pigs:
5 mg trimethoprim and 25 mg sulfamethoxazole per kg body weight a day, for 4-7 days. This corresponds to 1 ml of the veterinary medicinal product per 4.0 kg body weight per day.

Based on the recommended dose, daily water consumption, and the number and weight of the pigs to be treated, the exact daily concentration of the veterinary medicinal product required should be calculated according to the following formula:

$$\frac{\text{Mean body weight (kg) of pigs to be treate}}{\text{Mean daily water consumption (litre) per pi} \times 4.0} = \text{xx ml veterinary medicinal product per litre drinking water}$$

Broilers:
7.5 mg trimethoprim and 37.5 mg sulfamethoxazole per kg body weight a day, for 3 days. This corresponds to 1 ml of the veterinary medicinal product per 2.67 kg body weight per day. Based on the recommended dose, daily water consumption, and the number and weight of the birds to be treated, the exact daily concentration of the veterinary medicinal product required should be calculated according to the following formula:

$$\frac{\text{Mean body weight (kg) of birds to be treated}}{\text{Mean daily water consumption (litre) per bird} \times 2.67} = \text{xx ml veterinary medicinal product per litre drinking water}$$

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, the body weight and water consumption should be determined as accurately as possible.
The daily amount is to be added to the drinking water such that all medication will be consumed in 24 hours. Medicated drinking water and stock solutions should be freshly prepared every 24 hours. During the treatment period animals should not have access to water sources other than the medicated water. However, it should be ensured that animals always have sufficient water available. After the end of the medication period, the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of active substance. The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of the veterinary medicinal product may need to be adjusted accordingly.

10. WITHDRAWAL PERIODS

Pigs: Meat and offal: 8 days.
Chickens: Meat and offal: 5 days.

Not for use in birds producing or intended to produce eggs for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not freeze.

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: 1 year.
Shelf life after dilution or reconstitution according to directions: 24 hours.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 16849/5008

Pack sizes:
HDPE bottle of 1 litre, closed with a tamper proof HDPE screw cap.
HDPE container of 5 litres, closed with tamper proof HDPE screw cap.

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 contact details to report suspected adverse reactions:
Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands
Tel: 44 (0)1939 211200

Manufacturer responsible for batch release:
Genera Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

17. OTHER INFORMATION

Environmental properties:
Trimethoprim is persistent in soils.

Pom-V ('Veterinary medicinal product subject to prescription')
For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, I.e. Combined label and package leaflet {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metaxol 20/100 mg/ml solution for use in drinking water for pigs and chickens.

2. COMPOSITION

Each ml contains:

Active substances:
Trimethoprim 20 mg
Sulfamethoxazole 100 mg

Excipients:
N-methyl pyrrolidone 690,8 mg

Clear, pale yellow to brownish-yellow solution

3. PACKAGE SIZE

1 litre, 5 litres

4. TARGET SPECIES

Pigs (fattening pigs) and chickens (broilers).

5. INDICATIONS FOR USE

Fattening pigs:
Treatment and metaphylaxis of:
- Post-weaning diarrhoea caused by beta-haemolytic K88-positive, K99-positive or 987P *Escherichia coli* strains susceptible to trimethoprim-sulfamethoxazole.
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Broilers:
Treatment and metaphylaxis of
- Colibacillosis caused by *Escherichia coli* susceptible to trimethoprim-sulfamethoxazole.
- Coryza caused by *Avibacterium paragallinarum* susceptible to trimethoprim-sulfamethoxazole.

The presence of the disease in the group/flock must be established before the veterinary medicinal product is used.

6. CONTRAINDICATIONS

Do not use in animals suffering from severe liver or kidney disease, oliguria or anuria.
Do not use in animals with impaired haematopoietic systems.
Do not use in cases of hypersensitivity to sulphonamides or trimethoprim or any of the excipients.

7. SPECIAL WARNINGS

Special warnings for each target species:
Severely diseased animals can have a decreased appetite and water consumption. If necessary the concentration of the veterinary medicinal product in the drinking water may need to be adjusted to make sure that the recommended dosage is being consumed. However if the concentration of the veterinary medicinal product is increased too much, the intake of the medicated drinking water decreases for palatability reasons. Therefore water intake should be monitored regularly, especially in broilers.
In case of insufficient intake of water, pigs should be treated parenterally.

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and, if irritation occurs, seek medical attention. In the event of accidental ingestion, seek medical advice. Wash hands and contaminated skin immediately after handling the veterinary medicinal product.

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

Other precautions:
Not applicable.

Pregnancy, lactation or lay:
The safety of the veterinary medicinal product has not been established in pigs and chickens during pregnancy, lactation, lay or in animals intended for breeding.
Laboratory studies in rabbits and rats conducted with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects.
Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Do not combined with other veterinary medicinal products.

Overdose:
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Special restrictions for use and special conditions for use:
Not applicable.

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

8. ADVERSE REACTIONS

Pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity.

Chickens:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity, decreased drinking.

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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 {national system details}.

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

Route of administration: in drinking water use.
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11. WITHDRAWAL PERIODS

Pigs: Meat and offal: 8 days.
Chickens: Meat and offal: 5 days.
Not for use in birds producing or intended to produce eggs for human consumption.

12. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not freeze.

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

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14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 16849/5008

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Handelsweg 25
5531 AE Bladel
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Tel: 44 (0)1939 211200

Manufacturer responsible for batch release:
Genera Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

18. OTHER INFORMATION

Environmental properties:
Trimethoprim is persistent in soils.

POM-V ('Veterinary medicinal product subject to prescription')

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use by: __/__/___
Shelf life after first opening the immediate packaging: 1 year.
Shelf life after dilution or reconstitution according to directions: 24 hours.

21. BATCH NUMBER

Lot {number}

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

Keep out of the sight and reach of children.

Approved 14 May 2024