

**Part IB-2B**

**LABELLING**

**WITH TEAR-OPEN LEAFLET**

**1 LITRE BOTTLE / 5 LITRES CONTAINER**

**METAXOL 20/100 mg/ml  
SOLUTION FOR USE IN DRINKING WATER FOR PIGS AND CHICKENS**

**Label for immediate package  
with tear-open leaflet**

**PARTICULARS TO APPEAR ON THE IMMEDIATE 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 for pigs and chickens  
Trimethoprim / Sulfamethoxazole

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml solution contains:

Active substances:

Trimethoprim 20 mg

Sulfamethoxazole 100 mg

**3. PHARMACEUTICAL FORM**

Solution for use in drinking water

A clear pale yellow to brownish-yellow solution

**4. PACKAGE SIZE**

1 litre, 5 litres

**5. TARGET SPECIES**

Pigs (fattening pigs) and chickens (broilers).

**6. INDICATION(S)**

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**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Route of administration: for use in drinking water.

Read the package leaflet before use.

**8. 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.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP: {month/year}

Once opened/broached, use by: \_\_/\_\_/\_\_

Shelf life after first opening the immediate packaging: 1 year.

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

**11. SPECIAL STORAGE CONDITIONS**

Do not freeze.

**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.

*To be completed nationally*

**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 BV  
Handelsweg 25  
5531 AE Bladel  
The Netherlands

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 16849/5008

**17. MANUFACTURER’S BATCH NUMBER**

Lot{number}

**Inside of tear-open leaflet**  
**1 LITRE BOTTLE/5 LITRE CONTAINER**

## **PACKAGE LEAFLET**

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

### **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 BV  
Handelsweg 25  
5531 AE Bladel  
The Netherlands

Manufacturers responsible for batch release:

Genera Inc.  
Svetonedeljska cesta 2  
Kalinovica  
10436 Rakov Potok  
Croatia

### **2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

### **3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS**

Each ml solution contains:

Active substances:

Trimethoprim           20 mg  
Sulfamethoxazole 100 mg

Clear, pale yellow to brownish-yellow solution

### **4. INDICATIONS**

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 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 case of known hypersensitivity to sulphonamides or trimethoprim or any of the excipients.

**6. ADVERSE REACTIONS**

A diminished water intake in chickens may occur rarely.

Hypersensitivity reactions can occur rarely .

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this 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**

Pigs (fattening pigs) and chickens (broilers).

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

Route of administration: for use in drinking water.

The 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 amount of the veterinary medicinal product required can be calculated according to the following formula:

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

#### 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 amount of the veterinary medicinal product required can 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**

The body weight and water consumption should be determined as accurately as possible, to ensure a correct dosage.

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 products has to be adjusted accordingly.

## **10. WITHDRAWAL PERIODS**

Pig: Meat and offal: 8 days.

Chicken: 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 WARNINGS**

### Special warnings for each target species:

Severely diseased animals can have a decreased appetite and water consumption. If necessary the concentration of the VMP in the drinking water should be adjusted to make sure that the recommended dosage is being consumed. However if the concentration of the 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 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 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 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 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.

The excipient N-methylpyrrolidone (NMP) may damage unborn children; therefore, women of child bearing age must be very careful to avoid exposure via spillage onto the skin when administering the product. If you are pregnant, think you may be pregnant or are attempting to conceive, you should not administer the product.

This 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 product.

### Pregnancy, lactation or lay:

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay.

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

Do not combine with other veterinary medicinal products.

Overdose (symptoms, emergency procedures, antidotes):

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.

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**

April 2021

**15. OTHER INFORMATION**

Pack sizes: 1 litre and 5 litres.  
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**

{1 Litre bottle and 5 Litres container}

### **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 BV  
Handelsweg 25  
5531 AE Bladel  
The Netherlands

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

### **2. Name of the veterinary medicinal product**

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

### **3. Statement of the active substance (s) and other ingredients**

Each ml solution contains:  
Active substances:  
Trimethoprim 20 mg  
Sulfamethoxazole 100 mg

### **4. Pharmaceutical form**

Solution for use in drinking water.  
Clear, pale yellow to brownish-yellow solution

### **5. Package size**

1 litre, 5 litres

### **6. Indications**

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 product is used.

## **7. 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 case of known hypersensitivity to sulphonamides or trimethoprim or any of the excipients.

## **8. Adverse reactions**

A diminished water intake in chickens may occur rarely.

Hypersensitivity reactions can occur rarely.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this label 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**

Pigs (fattening pigs) and chickens (broilers).

## **10. Dosage for each species, route and method of administration**

Route of administration: in drinking water use.

The 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 amount of the veterinary medicinal product required can be calculated according to the following formula:

Mean body weight (kg) of pigs to be treated = xx ml veterinary medicinal product  
per litre drinking water  
Mean daily water consumption (litre) per pig x 4.0

### 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 amount of the veterinary medicinal product required can be calculated according to the following formula:

Mean body weight (kg) of birds to be treated = xx ml veterinary medicinal product  
per litre drinking water  
Mean daily water consumption (litre) per bird x 2.67

## 11. Advice on correct administration

The body weight and water consumption should be determined as accurately as possible, to ensure a correct dosage.

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 products has to be adjusted accordingly.

## 12. Withdrawal period(s)

Withdrawal periods:

Pig: Meat and offal: 8 days.

Chicken: Meat and offal: 5 days.

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

## 13. 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.

#### **14. 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 VMP in the drinking water should be adjusted to make sure that the recommended dosage is being consumed. However if the concentration of the 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.

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Special precautions to be taken by the person administering the veterinary medicinal product to animals:

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If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the physician this warning.

The excipient N-methylpyrrolidone (NMP) may damage unborn children; therefore, women of child bearing age must be very careful to avoid exposure via spillage onto the skin when administering the product. If you are pregnant, think you may be pregnant or are attempting to conceive, you should not administer the product.

This 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 product.

Pregnancy, lactation or lay:

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay.

Interaction with other medicinal products and other forms of interaction:

Do not combine with other veterinary medicinal products.

Overdose (symptoms, emergency procedures, antidotes):

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.

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**

April 2021

**17. Other information**

Pack sizes: 1 litre and 5 litres.

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.

**18. 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.

To be completed nationally

**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/broached, use by: \_\_/\_\_/\_\_

Shelf life after first opening the immediate packaging: 1 year.

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

**21. Marketing authorisation number(s)**

Vm 16849/5008

**22. Manufacturer's batch number**

Lot {number}

Approved: 01/07/21

