

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

1 KG BAGS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Soludox 500 mg/g powder for use in drinking water for turkeys
Soludox 433 mg/g powder for use in drinking water for turkeys (FR)

2. COMPOSITION

Each gram contains:

Active substance:

Doxycycline 433 mg (equivalent to 500 mg of doxycycline hyclate)

Excipients:

Tartaric acid 500 mg

Yellow crystalline powder.

3. PACKAGE SIZE

1 kg

4. TARGET SPECIES

Turkeys (for meat production, for reproduction).

5. INDICATIONS FOR USE

Indications for use

Treatment of clinical respiratory infections associated with *Mycoplasma gallisepticum* susceptible to doxycycline.

6. CONTRAINDICATIONS

Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Do not use in animals with hepatic and/or renal dysfunction.

Do not use when tetracycline resistance has been detected in the flock due to the potential for cross-resistance.

7. SPECIAL WARNINGS

Special warnings

Special warnings:

The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of drinking water, turkeys should be treated parenterally.

Special precautions for safe use in the target species:

Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to doxycycline and may decrease the effectiveness of treatment with other tetracyclines due to the potential for cross-resistance.

Due to likely variability (time, geographical) in susceptibility of bacteria for doxycycline bacteriological sampling and susceptibility testing are recommended. In particular susceptibility of *O.rhinotracheale* may differ from country to country and even farm to farm.

Use of the veterinary medicinal product should be based on culture and sensitivity of micro-organisms from diseased cases on farm. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. As eradication of the target pathogens may not be achieved, medication should therefore be combined with good management practices, e.g. good hygiene, proper ventilation, no overstocking.

Avoid administration in oxidised drinking equipment.

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

This veterinary medicinal product may cause contact dermatitis and/or hypersensitivity reactions if contact is made with the skin or eyes (powder and solution) or if the veterinary medicinal product is inhaled.

If you know you are allergic to the tetracycline class of antibiotics, special care should be taken when handling this veterinary medicinal product or the medicated solution.

During preparation and administration of the medicated drinking water, skin contact with the veterinary medicinal product and inhalation of dust particles should be avoided. Wear impermeable gloves (e.g. rubber or latex) and an appropriate dust mask (e.g. disposable half-mask respirator conforming to European Standard EN149) when applying the veterinary medicinal product.

In the event of eye or skin contact, rinse the affected area with large amounts of clean water and if irritation occurs, seek medical attention. Wash hands and contaminated skin immediately after handling the veterinary medicinal product.

If you develop symptoms following exposure such as skin rash, you should seek medical advice and show this warning to the physician. Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

Do not smoke, eat or drink while handling the veterinary medicinal product.

Take measures to avoid producing dust when incorporating the veterinary medicinal product into water.

Avoid direct contact with skin and eyes when handling the veterinary medicinal product to prevent sensitisation and contact dermatitis.

Pregnancy and lactation:

Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effect.

Laying birds:

Do not use in birds in lay and within 4 weeks before the start of the laying period.

Interaction with other medicinal products and other forms of interaction:

Do not administer in conjunction with bactericidal antibiotics such as beta-lactams as tetracyclines are bacteriostatic antimicrobials. Absorption of doxycycline can be decreased in the presence of high quantities of calcium, iron, magnesium or aluminium in the diet. Do not administer together with antacids, kaolin or iron preparations.

It is advised that the interval between the administration of other products containing polyvalent cations should be 1-2 hours because they limit the absorption of tetracyclines.

Doxycycline increases the action of anticoagulants.

The solubility of the product is pH-dependent and it will precipitate out if mixed in alkaline solutions.

Do not store the drinking water in metallic containers.

Overdose:

No adverse effects were observed after administration of doxycycline to turkeys at the fivefold therapeutic dose for up to 10 days. If suspected toxic reactions do occur due to extreme overdose, the medication should be discontinued and appropriate symptomatic treatment should be initiated if necessary.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products. See also section ‘Interaction with other medicinal products and other forms of interaction’.

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products or other substances used in drinking water.

8. ADVERSE EVENTS

Adverse events

Turkeys (for meat production, for reproduction):

Rare (1 to 10 animals / 10,000 animals treated):	Allergic reaction* Photosensitivity*
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*If suspected adverse events occur, treatment should be discontinued.

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 its local representative using the contact details on this label, or via your national reporting system: {national system details}.

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

Dosage for each species, routes and method of administration

In drinking water use.

Dosage: 25 mg doxycycline corresponding to 29 mg doxycycline hyclate per kg of body weight daily (equivalent to 58 mg veterinary medicinal product per kg of body weight), administered in the drinking water for 5 consecutive days.

The veterinary medicinal product should be administered continuously in the drinking water during the whole period of treatment.

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:

$$\frac{58 \text{ mg veterinary medicinal product / kg body weight per day} \times \text{average body weight (kg) of birds to be treated}}{\text{average daily water intake (l/animal)}} = \dots \text{ mg veterinary medicinal product per litre of drinking water}$$

To ensure a correct dosage, body weight should be determined as accurately as possible. The intake of medicated drinking water depends on the clinical condition of the birds. In order to obtain the correct dosage the concentration of doxycycline has to be adjusted accordingly. The use of suitably calibrated weighing equipment is recommended if part packs are used. The daily amount is to be added to the drinking water such that all medication will be consumed within 24 hours. Medicated drinking water should be refreshed or replaced every 24 hours. It is recommended to prepare a concentrated pre-solution - approximately 100 grams veterinary medicinal product per litre drinking water - and to dilute this further to therapeutic concentrations if required. Alternatively, the concentrated solution can be used in a proportional water medicator. Solubility of the veterinary medicinal product is pH-dependent and it may precipitate out if it is mixed in hard alkaline drinking water. Use at minimum concentrations of 200 mg powder per litre drinking water in areas with hard alkaline drinking water (hardness above 10.2°d and pH more than 8.1). During the treatment period birds should not have access to water sources other than the medicated water.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

11. WITHDRAWAL PERIODS

Withdrawal periods

Turkeys:

Meat and offal: 12 days.

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 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 NUMBERS AND PACK SIZES

Marketing authorisation numbers

Pack sizes

Bags of 1 kg.

Sachets of 100 grams packed per 10 in a carton box.

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

17. CONTACT DETAILS

Contact details

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

Manufacturer responsible for batch release:

Eurovet Animal Health B.V.

Handelsweg 25

5531 AE Bladel

The Netherlands

Local representatives and contact details to report suspected adverse events:

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

18. OTHER INFORMATION

Other information

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: 6 months.

Shelf life after dissolution according to directions: 24 hours.

21. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box 10x100 g only

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Soludox 500 mg/g powder for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

Active substance:

Doxycycline 433 mg (equivalent to 500 mg of doxycycline hyclate)

3. PACKAGE SIZE

10 x 100 g

4. TARGET SPECIES

Turkeys ((for meat production, for reproduction).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Turkeys:

Meat and offal: 12 days.

Not for use in birds producing eggs for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use by ...

Once opened use within 6 months.

Shelf life after dissolution according to directions: 24 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

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Sachet 100 g (10 per carton box)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Soludox 500 mg/g powder for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

Active substance:

Doxycycline 433 mg (equivalent to 500 mg of doxycycline hyclate)

3. TARGET SPECIES

Turkeys (for meat production, for reproduction).

4. ROUTES OF ADMINISTRATION

In drinking water use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Turkeys:

Meat and offal: 12 days.

Not for use in birds producing eggs for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months

Once dissolved use within 24 hours

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Soludox 500 mg/g powder for use in drinking water for turkeys

FR: Soludox 433 mg/g powder for use in drinking water for turkeys

2. Composition

Each gram contains:

Active substance:

Doxycycline 433 mg (equivalent to 500 mg of doxycycline hyclate)

Excipients:

Tartaric acid 500 mg

Yellow crystalline powder.

3. Target species

Turkeys (for meat production, for reproduction).

4. Indications for use

Treatment of clinical respiratory infections associated with *Mycoplasma gallisepticum* susceptible to doxycycline.

5. Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Do not use in animals with hepatic and/or renal dysfunction.

Do not use when tetracycline resistance has been detected in the flock due to the potential for cross-resistance.

6. Special warnings

Special warnings:

The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of drinking water, turkeys should be treated parenterally.

Special precautions for safe use in the target species:

Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to doxycycline and may decrease the effectiveness of treatment with other tetracyclines due to the potential for cross-resistance.

Due to likely variability (time, geographical) in susceptibility of bacteria for doxycycline bacteriological sampling and susceptibility testing are recommended. In particular susceptibility of *O.rhinotracheale* may differ from country to country and even farm to farm.

Use of the veterinary medicinal product should be based on culture and sensitivity of micro-organisms from diseased cases on farm. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. As eradication of the target pathogens may not be achieved, medication should therefore be combined with good management practices, e.g. good hygiene, proper ventilation, no overstocking.
Avoid administration in oxidised drinking equipment.

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During preparation and administration of the medicated drinking water, skin contact with the veterinary medicinal product and inhalation of dust particles should be avoided. Wear impermeable gloves (e.g. rubber or latex) and an appropriate dust mask (e.g. disposable half-mask respirator conforming to European Standard EN149) when applying the veterinary medicinal product.

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If you develop symptoms following exposure such as skin rash, you should seek medical advice and show this warning to the physician. Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

Do not smoke, eat or drink while handling the veterinary medicinal product.

Take measures to avoid producing dust when incorporating the veterinary medicinal product into water. Avoid direct contact with skin and eyes when handling the veterinary medicinal product to prevent sensitisation and contact dermatitis.

Pregnancy and lactation:

Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effect.

Laying birds:

Do not use in birds in lay and within 4 weeks before the start of the laying period.

Interaction with other medicinal products and other forms of interaction:

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It is advised that the interval between the administration of other products containing polyvalent cations should be 1-2 hours because they limit the absorption of tetracyclines.

Doxycycline increases the action of anticoagulants.

The solubility of the product is pH-dependent and it will precipitate out if mixed in alkaline solutions.

Do not store the drinking water in metallic containers.

Overdose:

No adverse effects were observed after administration of doxycycline to turkeys at the fivefold therapeutic dose for up to 10 days. If suspected toxic reactions do occur due to extreme overdose, the medication should be discontinued and appropriate symptomatic treatment should be initiated if necessary.

Major incompatibilities:

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

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products or other substances used in drinking water.

See also section ‘Interaction with other medicinal products and other forms of interaction.’

7. Adverse events

Turkeys (for meat production, for reproduction):

Rare (1 to 10 animals / 10,000 animals treated):	Allergic reaction* Photosensitivity*
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*If suspected adverse events occur, treatment should be discontinued.

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 its local representative 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

In drinking water use.

Dosage: 25 mg doxycycline corresponding to 29 mg doxycycline hyclate per kg of body weight daily (equivalent to 58 mg veterinary medicinal product per kg of body weight), administered in the drinking water for 5 consecutive days.

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9. Advice on correct administration

None.

10. Withdrawal periods

Turkeys:

Meat and offal: 12 days.

Not for use in birds producing eggs for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

This 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: 6 months.

Shelf life after dissolution according to directions: 24 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 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

Bags of 1 kg.

Sachets of 100 grams packed per 10 in a carton box.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

16. Contact details

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

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Eurovet Animal Health B.V.

Handelsweg 25

5531 AE Bladel

The Netherlands

Local representatives and contact details to report suspected adverse events:

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

17. Other information