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

1 KG BAGS

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release , if different

Marketing authorisation holder and manufacturer responsible for batch release:
Eurovet Animal Health BV
Handelsweg 25
5531 AE Bladel
The Netherlands

2. Name of the veterinary medicinal product

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

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

1 g powder contains:
Active substance:
Doxycycline hyclate 500 mg, corresponding to 433 mg doxycycline
Excipient:
Tartaric acid 500 mg

4. Pharmaceutical form

Yellow crystalline powder for use in drinking water.

5. Package size

1 kg

6. Indication(s)

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

7. Contraindications

Do not use in cases 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.

8. Adverse reactions

As for all tetracyclines, on rare occasions (more than 1 but less than 10 animals in 10,000 animals) allergic reactions and photosensitivity may occur. If suspected adverse reactions occur, treatment should be discontinued.
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.

9. Target species

Turkeys (broilers, breeders).

10. Dosage for each species, route(s) and method of administration

Administer orally in the drinking water.

Dosage: 25 mg doxycycline corresponding to 29 mg doxycycline hyclate per kg of body weight daily (equivalent to 58 mg product per kg of body weight), administered in the drinking water for 5 consecutive days.
The product should be administered continuously in the drinking water during the whole period of treatment. Based on the dosage to be used, and the number and weight of the birds to be treated, the exact daily amount of product required can be calculated.
The following formula can be used to calculate the concentration of the product in drinking water:

$$\frac{\text{58 mg product / kg body weight / day} \times \text{mean body weight (kg) of birds to be treated}}{\text{mean daily water consumption (l) per bird}} = \text{.... mg product per l drinking water}$$

To ensure a correct dosage, body weight should be determined as accurately as possible. The uptake 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 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 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.

11. Advice on correct administration

12. Withdrawal period(s)

Withdrawal period:
Meat and offal: 12 days.
Not authorised for use in birds producing eggs for human consumption.

13. 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 pack after EXP. The expiry date refers to the last day of that month.

14. Special warnings

Special warnings for each target species:
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 use in animals:
Official, national and regional antimicrobial policies should be taken into account when the product is used.
Use of the 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 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 product may cause contact dermatitis and/or hypersensitivity reactions if contact is made with the skin or eyes (powder and solution) or if the product is inhaled.
If you know you are allergic to the tetracycline class of antibiotics, special care should be taken when handling this product or the medicated solution.
During preparation and administration of the medicated drinking water, skin contact with the 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 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 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 product.
Take measures to avoid producing dust when incorporating the product into water. Avoid direct contact with skin and eyes when handling the product to prevent sensitisation and contact dermatitis.

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

Overdose (symptoms, emergency procedures, antidotes):
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.

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 products should be disposed of in accordance with local requirements.

16. Date on which the label was last approved

To be completed nationally

17. Other information

Pack sizes: 10 x 100 g and 1000 g.
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}

Shelf life after first opening the immediate packaging: 6 months.
Once opened, use by: _____/_____/_____
Shelf life after dilution or reconstitution according to directions: 24 hours.

21. Marketing authorisation number

Vm 16849/4046

22. Manufacturer's batch number

Lot: {number}

LABELLING 10 x 100 g

**Carton box for the 10 x 100 g Alufoil sachets
with label for 100 g sachets
and leaflet**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Carton 10 x 100 g only**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE

1 g powder contains:
Active substance:
Doxycycline hyclate 500 mg, corresponding to 433 mg doxycycline

3. PHARMACEUTICAL FORM

Powder for use in drinking water

4. PACKAGE SIZE

10 x 100 g

5. TARGET SPECIES

Turkeys (broilers, breeders).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administer orally in the drinking water.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 12 days.
Not authorised for use in birds producing eggs for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}
Shelf life after first opening the immediate packaging: 6 months.
Shelf life after dilution or reconstitution according to directions: 24 hours.

11. SPECIAL STORAGE CONDITIONS

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.

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

Vm 16849/4046

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Aluminium foil sachet 100 g (10 per carton)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 g powder contains:
Active substance:
Doxycycline hyclate 500 mg, corresponding to 433 mg doxycycline

3. PHARMACEUTICAL FORM

Powder for use in drinking water

4. PACKAGE SIZE

100 g

5. TARGET SPECIES

Turkeys (broilers, breeders).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administer orally in the drinking water.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 12 days.
Not authorised for use in birds producing eggs for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}

Shelf life after first opening the immediate packaging: 6 months.
Once opened, use by: _____/_____/_____
Shelf life after dilution or reconstitution according to directions: 24 hours.

11. SPECIAL STORAGE CONDITIONS

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.

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

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

Vm 16849/4046

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PACKAGE LEAFLET FOR:

Soludox 500 mg/g
Powder for use in drinking water for 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 and manufacturer responsible for batch release:
Eurovet Animal Health BV
Handelsweg 25
5531 AE Bladel
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

1 g powder contains:
Active substance:
Doxycycline hyclate 500 mg, corresponding to 433 mg doxycycline
Excipient:
Tartaric acid 500 mg
Yellow crystalline powder.

4. INDICATIONS

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

5. CONTRAINDICATIONS

Do not use in cases 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. ADVERSE REACTIONS

As for all tetracyclines, on rare occasions (more than 1 but less than 10 animals in 10,000 animals) allergic reactions and photosensitivity may occur. If suspected adverse reactions occur, treatment should be discontinued.

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.

7. TARGET SPECIES

Turkeys (broilers, breeders).

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

Administer orally in the drinking water.
Dosage: 25 mg doxycycline corresponding to 29 mg doxycycline hyclate per kg of body weight daily (equivalent to 58 mg product per kg of body weight), administered in the drinking water for 5 consecutive days.
The product should be administered continuously in the drinking water during the whole period of treatment. Based on the dosage to be used, and the number and weight of the birds to be treated, the exact daily amount of product required can be calculated.
The following formula can be used to calculate the concentration of the product in drinking water:

$$\frac{\text{58 mg product / kg body weight / day} \times \text{mean body weight (kg) of birds to be treated}}{\text{mean daily water consumption (l) per bird}} = \text{.... mg product per l drinking water}$$

To ensure a correct dosage body weight should be determined as accurately as possible. The uptake 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 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 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.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Meat and offal: 12 days.
Not authorised 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.
Shelf life after first opening the immediate packaging: 6 months.
Shelf life after dilution or reconstitution according to directions: 24 hours.
Do not use this veterinary medicinal product after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special warnings for each target species:
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 use in animals:
Official, national and regional antimicrobial policies should be taken into account when the product is used.
Use of the 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 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 product may cause contact dermatitis and/or hypersensitivity reactions if contact is made with the skin or eyes (powder and solution) or if the product is inhaled.
If you know you are allergic to the tetracycline class of antibiotics, special care should be taken when handling this product or the medicated solution.
During preparation and administration of the medicated drinking water, skin contact with the 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 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 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 product.
Take measures to avoid producing dust when incorporating the product into water. Avoid direct contact with skin and eyes when handling the product to prevent sensitisation and contact dermatitis.

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

Overdose (symptoms, emergency procedures, antidotes)
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.

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 products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

To be completed nationally

15. OTHER INFORMATION

Pack sizes: 10 x 100 g and 1000 g.
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.

Approved: 12/10/2017