PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{bag}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxycycline Hyclate VMD 500 mg/g Powder for Use in Drinking Water for Chickens

2. STATEMENT OF ACTIVE SUBSTANCES

Doxycycline hyclate 500 mg

3. PHARMACEUTICAL FORM

Powder for use in drinking water

4. PACKAGE SIZE

100 g
1 kg

5. TARGET SPECIES

Non-egg laying chickens.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
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, use by…
Once reconstituted, use by…

11. SPECIAL STORAGE CONDITIONS

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

V.M.D. n.v.
Hoge Mauw 900
2370 Arendonk
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 19968/4001.

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PACKAGE LEAFLET:
Doxycycline Hyclate VMD 500 mg/g Powder for Use in Drinking Water for Chickens

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

V.M.D. n.v.
Hoge Mauw 900
2370 Arendonk
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxycycline Hyclate VMD 500 mg/g Powder for Use in Drinking Water for Chickens
Doxycycline hyclate

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

One gram contains:

Active substance:
Doxycycline hyclate 500 mg
Excipients:
Citric Acid Anhydrous.
Lactose Monohydrate.

Homogeneous, fine, yellow powder.

4. INDICATION(S)

Treatment of the following specified infections of the respiratory tract and alimentary tract caused by micro-organisms susceptible to doxycycline.
Non-egg laying chickens:
Infections of the respiratory tract caused by *Mycoplasma spp, Escherichia coli, Avibacterium paragallinarum* and *Bordetella avium*.
Enteritis caused by *Clostridium perfringens* and *Clostridium colinum.*

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to tetracyclines or any of the excipients.
Do not administer to animals with severe liver or kidney insufficiency.

6. ADVERSE REACTIONS

None known.

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

Non-egg laying chickens.

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

Non-egg laying chicken: 25 mg doxycycline hyclate per kg bodyweight per day, corresponding to 50 mg of product per kg bodyweight, per day for 3-5 days.

Route of administration: For the administration through the drinking water, the exact daily amount of product should be calculated, based on the recommended dose, and the number and weight of the birds to be treated, according to the following formula:

Mg product per litre drinking water =
Mg product/kg bodyweight/day x mean bodyweight (kg) of birds to be treated
Mean daily water consumption (litre) per animal

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. The uptake of medicated water depends on the clinical conditions of the birds and the concentration of doxycycline should be adjusted accordingly. The daily amount is to be added to the drinking water such that all medication will be consumed in 24 hours. Medicated drinking water should be freshly prepared 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. Medicated water should be the only drinking source.
Use appropriately and properly calibrated dosing equipment.

9. ADVICE ON CORRECT ADMINISTRATION

Due to variability (time, geographical) in susceptibility of bacteria to doxycycline, bacteriological sampling and susceptibility testing of micro-organisms from diseased animals on farm are highly recommended.
A high resistance rate of *E.coli* isolated from chickens, against tetracyclines has been documented. Therefore the product should be used for the treatment of infections caused by *E.coli* only after susceptibility testing has been carried out.
As eradication of the target pathogen may not be achieved, medication should therefore be combined with good management practices e.g. good hygiene, proper ventilation, no overstocking.

10. WITHDRAWAL PERIOD(S)

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.
This veterinary medicinal product does not require any special storage conditions.
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 container: 28 days.
Shelf life after reconstitution according to directions: 24 hours.

When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the bag should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

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 powder is inhaled.
People with known hypersensitivity to tetracyclines should not handle the product.
Wear impermeable gloves (e.g. rubber or latex) and an appropriate dust mask (e.g. a disposable half-mask respirator conforming to European Standard EN 149 (FFP2) or a non-disposable respirator to European Standard EN 140 with a filter to EN 143) when applying the product.
Do not smoke, eat or drink while handling 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.

Lay:
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 combination with bactericidal antibiotics, such as penicillins and cephalosporins.

Doxycycline absorption may be reduced by the presence of high quantities of calcium, iron, magnesium or aluminium in the diet.

Overdose (symptoms, emergency procedures, antidotes):
Doxycycline has a high therapeutic index. The normal dose for oral use is 25 mg/kg bodyweight, where the LD50 for the most sensitive animal species is 1700 mg/kg bodyweight after oral administration.

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

Medicines should not be disposed of via wastewater. Dispose of any unused product and empty containers in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{DD month YYYY}

15. OTHER INFORMATION

Not all pack sizes may be marketed.
Marketing authorisation number: Vm 19968/4001.
100 g and 1 kg bags.
To be supplied only on veterinary prescription.
For animal treatment only.

Approved 19 February 2018