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

**{1 kg / 2 kg}**

## 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

Altidox 500 mg/g powder for use in drinking water for pigs, chickens and turkeys
Doxycycline

## 3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each g contains:
**Active substance:**
Doxycycline 433 mg
(equivalent to doxycycline hyclate 500 mg)

Yellow crystalline powder.

## 4. PHARMACEUTICAL FORM

Powder for use in drinking water.

## 5. PACKAGE SIZE

1 kg, 2 kg

## 6. INDICATIONS

Pigs: treatment of clinical respiratory infections caused by *Mycoplasma hyopneumoniae* and *Pasteurella multocida* susceptible to doxycycline.
Chickens and turkeys: treatment of clinical respiratory infections associated with *Mycoplasma gallisepticum* susceptible to doxycycline.

## 7. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to tetracyclines or to the excipients.
Do not use when tetracycline resistance has been detected in the herd/flock due to the potential for cross-resistance.
Do not use in animals with impaired liver or kidney function.

## 8. ADVERSE REACTIONS

As for all tetracyclines, on rare occasions (more than 1 but less than 10 animals in 10,000 animals treated) 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.

<Alternatively you can report via your national reporting system {national system details}.>*[For MRP/DCP only]*

## 9. TARGET SPECIES

Target species:
Pig (post-weaning), chicken (broilers, pullets, breeders) and turkey (broilers, pullets, breeders).

## 10. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

In drinking water use.
*Dosage:*
In pigs and chickens:
20 mg doxycycline per kg body weight daily (equivalent to 46 mg product per kg body weight), administered in the drinking water for 5 consecutive days.

In turkeys:
25 mg doxycycline per kg body weight daily (equivalent to 58 mg product per kg body weight), administered in the drinking water for 5 consecutive days.

*Administration:*
Based on the recommended dosage, and the number and weight of the animals to be treated, the exact daily amount of the product to be administered should be calculated according to the following formula:

$$\frac{\text{…. mg product per kg body weight per day} \times \text{mean body weight (kg) of animals to be treated}}{\text{mean daily water consumption (litre per animal)}} = \text{…. mg product per litre of drinking water}$$

## 11. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.
The uptake of medicated water is dependent on the clinical condition of the animals. In order to obtain the correct dosage, the concentration in drinking water may have to be adjusted. 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 in such a way that all medication will be consumed within 24 hours. Medicated drinking water should be freshly prepared every 24 hours. It is recommended to prepare a concentrated pre-solution and to dilute this further to therapeutic concentrations, if required. Alternatively; the concentrated solution can be used in a proportional water medicator. The maximum solubility of the product in water is at least 100 g/L.
It should be ensured that all animals intended to be treated should have free access to the drinking facilities. At the end of treatment, the watering equipment should be cleaned adequately to avoid the uptake of remaining quantities in sub-therapeutic doses. The medicated water should be the only source of drinking water throughout the treatment period. The medicated water must not be made or stored in a metal container or used in oxidised drinking equipment. Solubility of the product is pH-dependent and it may precipitate if it is mixed in hard alkaline drinking water.

## 12. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Meat and offal: Pigs: 4 days
Chickens: 5 days
Turkeys: 12 days
Not authorised for use in birds producing eggs for human consumption.

## 13. SPECIAL STORAGE PRECAUTIONS

Keep the bag tightly closed after first opening in order to protect from moisture.
This veterinary medicinal product does not require any special temperature storage conditions. Do not use this veterinary medicinal product after the expiry date which is stated on this packaging 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, animals should be treated parenterally.

Special precautions for use in animals:
The safety of the product has not been established in piglets before weaning.
Inappropriate use of the product may increase the prevalence of bacteria resistant to tetracyclines due to the potential for cross-resistance.

Due to variability (time, geographical) in susceptibility of bacteria for doxycycline, bacteriological sampling and susceptibility testing of micro-organisms from diseased animals on farm are highly recommended.
Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target bacteria at farm level, or at local/regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies.
Avoid administration in oxidized drinking equipment.
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.

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.
- 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.
- People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product. 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 or a non-disposable respirator to European Standard EN140 with a filter to EN143) 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.
- Do not smoke, eat or drink while 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.
Pregnancy and lactation:
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.
The safety of the product has not been established in pregnant or lactating sows. Use is not recommended during pregnancy or lactation.

Lay:
Do not use in birds in lay or within 4 weeks before the onset of the laying period.

Interaction with other medicinal products and other forms of interaction:
Do not administer concurrently with feed overloaded with polyvalent cations such as $Ca^{2+}$, $Mg^{2+}$, $Zn^{2+}$ and $Fe^{3+}$ because the formation of doxycycline complexes with these cations is possible. It is advised that the interval between administration of other

products containing polyvalent cations should be 1-2 hours because they limit the absorption of tetracycline.
Doxycycline has a low affinity for forming complexes with calcium and studies have demonstrated that doxycycline scarcely affects skeleton formation.
Do not administer together with antacids, kaolin or iron preparations.
Do not administer in conjunction with bactericidal antibiotics such as beta-lactams as tetracyclines are bacteriostatic antimicrobials.
Doxycycline increases the action of anticoagulants.

Overdose (symptoms, emergency procedures, antidotes):
During the target animal tolerance study, no adverse effects were observed in any of the target species, even at the fivefold therapeutic dose administered for two times the recommended duration.
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

July 2021

## 17. OTHER INFORMATION

Pack sizes: 1 kg and 2 kg.
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.

## 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 of the bag: 3 months.
Shelf life after dilution or reconstitution according to directions: 24 hours.

## 21. MARKETING AUTHORISATION NUMBER(S)

Vm 16849/4056

## 22. MANUFACTURER'S BATCH NUMBER

Lot {number}

Approved 11 August 2021