PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

1 kg / 2 kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Altidox 500 mg/g powder for use in drinking water for pigs, chickens and turkeys
Altidox 433 mg/g powder for use in drinking water for pigs, chickens and turkeys (FR)
Citridox 500 mg/g powder for use in drinking water for pigs, chickens and turkeys (PT)

2. COMPOSITION

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

Yellow crystalline powder.

3. PACKAGE SIZE

1 kg, 2 kg

4. TARGET SPECIES

Pigs (for fattening, for reproduction and weaned piglets), chickens (broiler, pullets) and turkeys (for meat production, for reproduction and poults).

5. INDICATIONS FOR USE

Indications for use
<u>Pigs:</u> treatment of clinical respiratory infections caused by *Mycoplasma hyopneumoniae* and *Pasteurella multocida* susceptible to doxycycline.
<u>Chickens and turkeys</u>: treatment of clinical respiratory infections associated with *Mycoplasma gallisepticum* susceptible to doxycycline.

6. CONTRAINDICATIONS

Contraindications
Do not use in cases of hypersensitivity to the active substance or to any of 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.

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, animals should be treated parenterally.

Special precautions for safe use in the target species:
The safety of the veterinary medicinal product has not been established in piglets before weaning.
Inappropriate use of the veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 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 powder is inhaled.
- 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.
- 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 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 or a non-disposable respirator to European Standard EN140 with a filter to EN143) 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.
- Do not smoke, eat or drink while handling the veterinary medicinal product.

If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the package leaflet or the label 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 veterinary medicinal product has not been established in pregnant or lactating sows. Use is not recommended during pregnancy or lactation.

Laying birds:
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-lactames as tetracyclines are bacteriostatic antimicrobials.
Doxycycline increases the action of anticoagulants.

Overdose:
During the target animal tolerance study, no adverse effects were observed in any of the target animal 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.

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.

8. ADVERSE EVENTS

Adverse events

Pigs (for fattening, for reproduction and weaned piglets), chickens (broiler, pullets) and turkeys (for meat production, for reproduction and poults):

Rare (1 to 10 animals / 10,000 animals treated):	Allergic reaction* Photosensitivity (abnormal skin reaction to light)*

*If suspected adverse reactions 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:
In pigs and chickens

20 mg doxycycline per kg body weight daily (equivalent to 46 mg veterinary medicinal 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 veterinary medicinal product per kg body weight), administered in the drinking water for 5 consecutive days.
Administration:
Based on the recommended dose and the number and weight of the animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

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

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration
To ensure a correct dosage, body weight should be determined as accurately as possible.
The intake 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 veterinary medicinal 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 veterinary medicinal product is pH-dependent and it may precipitate if it is mixed in hard alkaline drinking water.

11. WITHDRAWAL PERIODS

Withdrawal periods
Meat and offal:
Pigs: 4 days.
Chickens: 5 days.
Turkeys: 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.

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 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 national collection systems applicable to the veterinary medicinal product concerned.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

These measures should help to protect the environment.

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
1 kg and 2 kg.

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 of the immediate packaging: 3 months.
Shelf life after dissolution according to directions: 24 hours.

21. BATCH NUMBER

Lot {number}