Label-leaflet

FLUID-DOX / ORIDOX / POWDOX /SOLDOXIN 100 mg/ml oral solution for use in drinking water for chickens and pigs
Doxycycline

1-L bottles
5-L barrels

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

Marketing authorisation holder:

VETPHARMA ANIMAL HEALTH, S.L.
Les Corts, 23
08028 Barcelona
SPAIN

Manufacturer for the batch release:

LABORATORIOS KARIZOO, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 – CALDES DE MONTBUI (Barcelona)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

POWDOX 100 mg/ml oral solution for use in drinking water for chickens and pigs
Doxycycline

3. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition per ml:

Active substance:
Doxycycline.....100 mg
(equivalent to Doxycycline hyclate 116.0 mg)

4. PHARMACEUTICAL FORM

Oral solution for use in drinking water.
Clear, dense, brownish-yellow solution.

5. TARGET SPECIES

Chicken (broilers) and pigs.

6. INDICATIONS

CHICKENS (BROILERS)
Prevention and treatment of chronic respiratory disease (CRD) and mycoplasmosis caused by microorganisms sensitive to doxycycline.

PIGS
Prevention of clinical respiratory disease due to *Pasteurella multocida* and *Mycoplasma hyopneumoniae* sensitive to doxycycline.

The presence of the disease in the herd should be established before treatment.

7. CONTRAINDICATIONS

Do not use in case of hypersensitivity to tetracyclines.
Do not use in cases of resistance to tetracyclines.
Do not use in animals with hepatic dysfunction.

8. ADVERSE REACTIONS

Allergic and photosensitivity reactions can occur. Intestinal flora may be affected if treatment is very prolonged, and this may result in digestive disturbance.
If suspected adverse reactions occur, treatment should be discontinued.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

9. METHOD AND ROUTE OF ADMINISTRATION

ORAL ROUTE, IN DRINKING WATER

The following dosage advice should be followed:

- CHICKEN (broilers): 11.5 – 23 mg doxycycline hyclate / kg body weight / day, corresponding to 0.1 -0.2 ml of the veterinary product per kg body weight, for 3-5 consecutive days. .

- PIGS: 11.5 mg doxycycline hyclate/ kg body weight / day, corresponding to 0.1 ml of the veterinary product per kg body weight, for 5 consecutive days.

Based on the recommended dose, and the number and weight of the animals to be treated, the exact daily amount of the veterinary product should be calculated according to the following formula:

$$\frac{\text{X ml veterinary product/ kg b.w./day} \times \text{Mean body weight (kg) of animals to be treated}}{\text{Mean daily water consumption (l) per animal}} = \text{X ml veterinary product per l drinking water}$$

Medicated water should be the only drinking source.

10. 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 dependant 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 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.
The remaining medicated water should be disposed of in accordance with local requirements.

If no improvement in clinical signs is seen within the treatment duration, the diagnosis should be reviewed and treatment changed.

11. WITHDRAWAL PERIOD

Meat & offal:
Chickens (broilers): 7 days.
Pigs: 7 days.

Eggs: Not permitted for use in laying birds producing eggs for human consumption

12. SPECIAL WARNINGS, IF NECESSARY

Special warnings for each target species
Sick animals may have a reduced appetite and altered drinking patterns and should, if necessary, be medicated parenterally.
In cases of altered food or drinking water uptake, the concentrations should be adjusted in such a way that the recommended dosage is achieved.

Use during pregnancy, lactation or lay

The product should not be used during pregnancy or lactation.

Special precautions for use in animals
Prolonged or repeated use of this veterinary medicinal product is discouraged. Attention should be paid to avoidance of stressful conditions and improvement of management practices and hygiene standards.
Avoid administration in oxidised drinking equipment.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional and farm level) epidemiological information about susceptibility of the target bacteria, taking into account official national antimicrobial policies. Inappropriate use of the product may increase the prevalence of bacteria resistant to doxycycline and may decrease the effectiveness of treatment with 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 birds 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 pathogens may not be achieved, medication should therefore be combined with good management practices, e.g. good hygiene, proper ventilation, no overstocking.

Doxycycline absorption may be reduced by the presence of high quantities of calcium, iron, magnesium or aluminium in the diet. Do not administer together with antacids, kaolin and iron preparations.
Do not administer together with bactericidal antibiotics.
The solubility of the product is pH dependent and will precipitate if mixed in alkaline solution.
Do not administer with milk replacers.

USER WARNINGS:

Tetracyclines may – in very rare cases – induce photosensitivity and allergic reactions.
Do not handle the product if you are hypersensitive to tetracyclines.
Wear gloves, work overall and approved safety glasses.
This product is acid and likely to be irritant. Avoid contact with skin and eyes. In case of contact with skin, rinse immediately with plenty of water. In case of contact with eyes, rinse immediately with copious amounts of water and seek medical advice.
Do not smoke, eat or drink while handling this product.
The product can be harmful by skin contact and inhalation and may cause eye irritation.
In case of accidental ingestion seek medical advice and show the label to the doctor.
If any symptom should appear, such as a cutaneous eruption, seek prompt medical advice. Swelling of the face, lips or eyes or respiratory difficulties are the most serious signs which require urgent medical attention.

Incompatibilities

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

Overdose (symptoms, emergency procedures, antidotes)

No data available.

13. EXPIRY DATE

EXP:
Once diluted, use within 24 hours.
Once opened, use within 28 days.

14. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.
Protect from light.

15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

For animal treatment only
Keep out of the reach and sight of children

Date on which the package leaflet was last approved:

Marketing authorisation number:

Vm 32509/4006

Batch:

To be supplied only on veterinary prescription

Approved 01 March 2018