

## **LABELLING AND PACKAGE LEAFLET**

**A. LABELLING**

**<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>**

{ 1 kg bag; 400 g bag}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**HydroDoxx 500 mg/g Powder for use in drinking water**  
for chickens and pigs  
Doxycycline (as doxycycline hyclate)

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

One gram contains:

Active substance: Doxycycline (as doxycycline hyclate) 500 mg

**3. PHARMACEUTICAL FORM**

Powder for use in drinking water  
Yellow powder

**4. PACKAGE SIZE**

1 kg  
400 g

**5. TARGET SPECIES**

Broilers  
Fattening pigs,

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

In drinking water use  
Only sufficient medicated drinking water should be prepared to cover daily requirements.  
Medicated drinking water should be refreshed or replaced every 24 hours.  
Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Meat and offal:

Pigs: 6 days

Chickens (broilers): 6 days

Not authorised for use in laying birds producing eggs for human consumption

Do not use within 4 weeks of onset of the laying period

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

<EXP {month/year}>

Once opened, use immediately

**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 REACH AND SIGHT OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Huvepharma NV  
Uitbreidingstraat 80  
2600 Antwerpen  
Belgium

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 30282/4012

**17. MANUFACTURER'S BATCH NUMBER**

<Batch><Lot><BN> {number}

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### **HydroDoxx 500 mg/g Powder**

for chickens and pigs

Doxycycline (as doxycycline hyclate)

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

##### Marketing authorisation

Huvepharma NV

Uitbreidingstraat 80

2600 Antwerpen, Belgium

Tel: +32 3 288 1849

Fax: +32 3 289 7845

e-mail: [customerservice@huvepharma.com](mailto:customerservice@huvepharma.com)

##### Manufacturer

BIOVET JSC

39 Petar Rakov Str.

4550 Peshtera – Bulgaria

Tel.: 359-350-65619

Fax.: 359-350-65636

e-mail: [biovet@biovet.com](mailto:biovet@biovet.com)

#### **2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

### **HydroDoxx 500 mg/g Powder for use in drinking water**

for chickens and pigs

Doxycycline (as doxycycline hyclate )

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

One gram contains:

Active substance:

Doxycycline (hyclate).....500 mg

#### **4. INDICATION(S)**

Chickens (broilers) :Prevention and Treatment of Chronic Respiratory Disease (CRD) caused by *Mycoplasma gallisepticum* susceptible to doxycyclin

Fattening pigs: prevention and treatment of clinical respiratory infection caused by sensitive strains of *Pasteurella multocida*. susceptible to doxycyclin

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, farm level) epidemiological information about susceptibility of the target bacteria.

The presence of the clinical disease in the herd/flock should be established before preventive treatment is started.

#### **5. CONTRAINDICATIONS**

Do not use in cases of hypersensitivity to the active substance, to other tetracyclines or to any excipient Do not use in animals with hepatic disorders.

Do not use in animals with renal disorders

#### **6. ADVERSE REACTIONS**

Allergic reactions.

Photosensitivity reactions.

If suspected adverse reactions occur, treatment should be discontinued. Inform your veterinary surgeon if adverse reactions occur that are not indicated

#### **7. TARGET SPECIES**

Chickens (broilers)

Pigs (fattening pigs)

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

In drinking water use

Chickens (broilers): 20 mg of doxycycline (equivalent to 40 mg of the veterinary medicinal product )/ kg BW / day for 3 - 5 days

Fattening pigs: 10 mg of doxycycline (equivalent to 20 mg of the veterinary medicinal product) / kg b.w / day for 5 days.

#### **9. ADVICE ON CORRECT ADMINISTRATION**

The following dosage advice should be followed:

For the preparation of the medicated water the body weight of the animals to be treated and their actual daily water intake should be taken into due account.

Consumption may vary depending on factors like age, state of health, breed, husbandry system.

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

$$\frac{\text{..... mg hydroDoxx/ kg bodyweight / day}}{\text{Mean daily water consumption (l) per animal}} \times \frac{\text{Mean body weight (kg) of the animals to be treated}}{\text{Mean body weight (kg) of the animals to be treated}} = \frac{\text{.....mg hydroDoxx/ l of drinking water}}{\text{l of drinking water}}$$

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 conditions of the animals . In order to obtain the correct dosage the concentration in drinking water may have to be adjusted. Do not use at concentrations lower than 0.23 g of powder /l in drinking water with pH higher or equal to 7.5 to avoid precipitation.

Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. No other source of drinking water should be available during the medication period.

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.

## 10. WITHDRAWAL PERIOD

Meat and offal

Pigs: 6 days

Chickens : 6 days

Not authorised for use in laying birds producing eggs for human consumption.

Do not use within 4 weeks of onset of the laying period

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children

This veterinary medicinal product does not require any special storage conditions.

Shelf life after reconstitution in medicated water: 24 hours

After first opening the container: discard the unused veterinary medicinal product.

Do not use after the expiry date stated on the label

## 12. SPECIAL WARNING(S)

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. If this is not possible, therapy should be based on local (regional and farm level) epidemiological information about susceptibility of the target bacteria as well as by taking into account official national antimicrobial policies.

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

Under-dosing and/or treating for an insufficient length of time are considered to promote the development of resistance in bacteria and should be avoided.

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

Avoid administration in oxidised drinking equipment.

Inappropriate use of the veterinary medicinal product 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.

Do not use at concentrations lower than 0.23 g of powder /l in drinking water with pH higher or equal to 7.5 to avoid precipitation.

Do not add acid to the medicated drinking water.

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) 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

The veterinary medicinal product should not be used during pregnancy or lactation

Do not use within 4 weeks of onset of the laying period. Do not use in laying birds producing eggs for human consumption

Do not administer jointly with bactericidal antibiotics (penicillins, aminoglycosides, etc)

Absorption of doxycycline can be decrease in the presence of high quantities of calcium, iron, magnesium or aluminum in the diet. Do not administered together with antiacids, kaolin and iron preparations.

It is advised that interval between administration other veterinary medicinal 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 veterinary medicinal product is pH dependent and will precipitate if mixed in alkaline solution.

Do no store the drinking water in metallic containers

The administration of 40 mg/kg bw in pigs and 80 mg/kg in chickens (in both species 4 times the recommended dose), for 5 days did not cause any adverse reaction.

In case of overdose treatment should be suspended and symptomatic treatment established.

In 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**

### **15. OTHER INFORMATION**

Bag of 1 kg or 400 g formed from polyethylene/aluminium/polyethylene terephthalate laminate.

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: 23 August 2018