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

Manufacturer

1. LABORATORIOS CALIER, S.A.
C/ Barcelonès, 26. Pla delRamassà.
08520 LES FRANQUESES DEL VALLÈS.
BARCELONA.
Tel: +34 93 849 51 33
Fax: +34 93 840 13 98
e-mail: laboratorios@calier.es

2. BIOVET JSC
39 Petar Rakov Str.
4550 Peshtera – Bulgaría
Tel.: 359-350-65619
Fax.: 359-350-65636
e-mail: 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

Yellow powder.

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 excipientDo 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:

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

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 doxycyclin 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

Heat-sealed bags of 1 kg formed from polyester/aluminium/low density polyethylene laminate
Cardboard drum containing 5 sachets of 1 kg
Cardboard drum containing 25 sachets of 1 kg"

Bag of 1 kg formed from polyethylene/aluminium/polyethylene terephtalate 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.