LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bag of 1 kg and 5 kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GalluDoxx 500 mg/g powder for use in drinking water/milk replacer for calves, chickens and turkeys.

Doxycyline hyclate

2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES

1 gram contains:
Doxycycline hyclate 500 mg (equivalent to 433 mg doxycycline)

3. PHARMACEUTICAL FORM

Powder for use in drinking water/milk replacer

4. PACKAGE SIZE

1 kg (5 kg)

5. TARGET SPECIES

Cattle (pre-ruminant calves)
Chickens (broilers, breeders, replacement pullets) and turkeys.

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE OF ADMINISTRATION

Oral use, after dissolution in drinking water/milk replacer.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period

Calves:	Meat and offal: 28 days
Turkeys:	Meat and offal: 28 days
Chickens	Meat and offal: 14 days

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

9. SPECIAL WARNING(S)

Read the package leaflet before use.

10. EXPIRY DATE

Exp <<EXP month/year>>
Shelf life after first opening of the immediate packaging: 3 months.
Shelf life after reconstitution in drinking water: 24 hours.
Shelf life after reconstitution in milk replacer: Use immediately. Do not store.

Once opened, use by:

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special temperature storage conditions. After first opening keep the bag tightly closed in order to protect from moisture.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Huvepharma N.V.
Uitbreidingstraat 80
B-2600 Antwerp
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 30282/4031

17. MANUFACTURER'S BATCH NUMBER

Batch <<number>>

PACKAGE LEAFLET

PACKAGE LEAFLET FOR

GalluDoxx 500 mg/g powder for use in drinking water/milk replacer for calves, chickens and turkeys

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

Marketing authorisation holder:
Huvepharma N.V.
Uitbreidingstraat 80
B-2600 Antwerp
Belgium

Manufacturer responsible for the batch release:
Biovet JSC
39 Petar Rakov Str,
4550 Peshtera
Bulgaria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

GalluDoxx 500 mg/g powder for use in drinking water/milk replacer for calves, chickens and turkeys

Doxycycline hyclate

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

Active substance:
Doxycycline hyclate 500 mg (equivalent to 433 mg doxycycline)

Yellowish powder.

4. INDICATION

Cattle (pre-ruminant calves)
For the treatment of:
- Pneumonia and shipping fever caused by *Pasteurella* spp. and *Mannheimia haemolytica* infections.

Chickens (broilers, breeders, replacement pullets) and turkeys
For the treatment of:
- Ornithosis caused by *Chlamydophila psittaci* in turkeys;
- Colibacillosis caused by *E. coli* in chickens and turkeys;
- Chronic Respiratory Disease caused by *Mycoplasma gallisepticum* in chickens and turkeys.

5. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to tetracyclines or the excipient.
Do not administer to animals with severe liver or kidney insufficiency.
Do not use when tetracycline resistance has been detected in the herd/flock due to the potential for cross resistance.

6. ADVERSE REACTIONS

Tetracyclines may in rare cases induce photosensitivity and allergic reactions. If suspected adverse reactions occur, treatment should be discontinued.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

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.

7. TARGET SPECIES

Cattle (pre-ruminant calves)
Chickens (broilers, breeders, replacement pullets) and turkeys.

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

Route of administration:

Calves: To be administered in drinking water/milk replacer
Chickens and turkeys: In drinking water use

Dosing

Cattle (pre-ruminant calves)

Doxycycline hyclate 5 mg per kg body weight, twice a day, equivalent to 10 mg of the product per kg of animal body weight, twice a day, for 4-7 successive days.

Chickens (broilers, breeders, replacement pullets) and turkeys:

20 mg doxycycline hyclate per kg of body weight per day, corresponding to 40 mg of the product per kg of animal body weight, for 4-7 consecutive days.

9. ADVICE ON CORRECT ADMINISTRATION

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

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

To ensure a correct dosage body weight should be determined as accurately as possible.
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.
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 12 hours. Medicated drinking water should be freshly prepared every 12 hours. It is recommended to prepare a concentrated pre-solution - not exceeding 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 water should be stirred until full dissolution of the product is obtained. The solubility of doxycycline decreases at higher pH. Therefore the product should not be used in hard alkaline water since precipitation might occur depending on the product concentration. Delayed precipitation might also occur.
Milk replacer: The veterinary medicinal product must first be dissolved in warm water before adding the milk powder - the maximal concentration to be used is 100 grams of product per litre of water. The obtained milk replacer solution must be homogenised and heated to feeding temperature prior to administration. The medicated milk replacer should should be freshly prepared prior to use, used immediately and be constantly stirred to avoid sedimentation of the active substance.
. If a concentration greater than 200 mg per litre of milk is required, animals should be treated parenterally.
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. At the end of treatment period the water supply should be cleaned adequately to avoid the uptake of remaining quantities in sub-therapeutic doses.

10. WITHDRAWAL PERIOD

Calves:	Meat and offal: 28 days
Turkeys:	Meat and offal: 28 days
Chickens	Meat and offal: 14 days

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions. After first opening keep the bag tightly closed in order to protect from moisture.

Do not use this veterinary medicinal product after expiry date which is stated on the label after exp. The expiry date refers to the last day of the month.
Shelf life after first opening the container: 3 months.
Shelf life after reconstitution in drinking water: 24 hours.
Shelf life after reconstitution in milk replacer: Use immediately. Do not store.

12. 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 or medicated milk replacer, animals should be treated parenterally It is necessary to administer medicated milk to calves on an individual basis.

Special precautions for use in animals

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.

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.

Official, national and regional antimicrobial policies should be taken into account when the product is used.

Use of the product deviating from the instructions given in the package leaflet 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.

Resistance to tetracyclines has also been reported in calf pathogens (*Pasteurella* spp.) in some EU countries.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

This product may cause contact dermatitis if contact is made with the eyes (powder or solution), or if the product is inhaled.Take measures to avoid producing dust when incorporating the product into water.
Avoid 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.

Interactions with other medicinal products and other forms of interaction

Do not use in conjunction with bactericidal antibiotics, such as penicillins and cephalosporins.
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. Do not administer together with antacids, kaolin and iron preparations. It is advised that the interval between administration of the product and administration of products containing polyvalent cations should be 1-2 hours because the latter limit the absorption of doxycycline.
Doxycycline increases the action of anticoagulants.

Overdose (symptoms, emergency procedures, antidotes)

In calves acute, sometimes fatal cardiac muscle degeneration may occur after one or more administrations. Since this is usually related to overdosing, it is important to calculate the dose correctly.

If suspected toxic reactions do occur due to extreme overdose, the medication should be discontinued and appropriate symptomatic treatment should be initiated if necessary.

Lay

Laboratory studies with doxycycline in rats and rabbits has not produced any evidence of teratogenic, embryotoxic or foetotoxic effects.
The safety of the product has not been assessed in breeder chickens. Use only accordingly to benefit/risk assessment by the responsible veterinarian.

Incompatibilities

In the 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 PRODUCTS OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2022

15. OTHER INFORMATION

Pack sizes:
Bag of 1 kg
Bag of 5 kg

Not all pack sizes may be marketed.

Approved 31 May 2022