A. LABELLING (5, 10 and 25 Kg package size)

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard drums containing 5 bags of 1 kg.
Cardboard drums containing 10 bags of 1 kg.
Cardboard drums containing 25 bags of 1 kg.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DOXYCYCLINE CALIER 500 mg/g POWDER FOR USE IN DRINKING WATER FOR CHICKENS, TURKEYS AND PIGS
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

5 kg (5 x 1 kg)
10 kg (10 x 1 kg)
25 kg (25 x 1 kg)

5. TARGET SPECIES

Chickens (broilers)
Pigs (fattening pigs)
Turkeys

6. INDICATIONS

Chickens (broilers) and turkeys: Prevention and treatment of Chronic Respiratory Disease (CRD) caused by *Mycoplasma gallisepticum* susceptible to doxycyclin.
Pigs (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 disease in the herd should be established before treatment.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Pigs:
Meat and offal: 6 days

Chickens:
Meat and offal: 6 days
Eggs: Not authorized for use in laying birds producing eggs for human consumption.

Turkeys
Meat and offal: 9 days

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
After first opening the immediate packaging, discard the unused veterinary medicinal product.

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.
Shelf-life after dilution in drinking water: 24 hours.

12. 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

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

Marketing authorisation holder and manufacturer
LABORATORIOS CALIER, S.A.
C/ Barcelonès, 26. Pla del Ramassà.
08520 LES FRANQUESES DEL VALLÈS.
BARCELONA. SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

B. INMEDIATE AND PACKAGE LEAFLET

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

Marketing authorisation holder and manufacturer
LABORATORIOS CALIER, S.A.
C/ Barcelonès, 26. Pla del Ramassà.
08520 LES FRANQUESES DEL VALLÈS.
BARCELONA. SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

DOXYCYCLINE CALIER 500 mg/g POWDER FOR USE IN DRINKING WATER FOR CHICKENS, TURKEYS AND PIGS
Doxycycline (hyclate)

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

One gram contains:
Active substance:
Doxycycline (as doxycycline hyclate) ..... 500 mg

4. INDICATION(S)

Chickens (broilers) and turkeys: Prevention and treatment of Chronic Respiratory Disease (CRD) caused by *Mycoplasma gallisepticum* susceptible to doxycyclin.
Pigs (fattening pigs): prevention and treatment of clinical respiratory infection caused by sensitive strains of *Pasteurella multocida* susceptible to doxycycline.
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 disease in the herd should be established before treatment.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to tetracyclines the active substance or to any excipient.
Do not use in animals with hepatic disorders.
Do not use in animals with renal disorders.

6. ADVERSE REACTIONS

In the case of allergic and/or photosensitivity reactions, the withdrawal of the treatment should be recommended.
Intestinal flora may be affected if treatment is very prolonged, and this may result in digestive disorder.
If suspected adverse reactions occur, treatment should be discontinued. Inform your veterinary surgeon if adverse reactions occur that are not indicated**.**
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens (broilers) and turkeys
Pigs (fattening pigs)

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

In drinking water use.

Chickens (broilers): 20 mg doxycycline (equivalent to 40 mg of product)/ kg b.w. / day for, 3-5 days

Turkeys: 20 mg doxycycline (equivalent to 40 mg of product)/ kg b.w. / day for, 5 days

Pig (fattening pigs): 10 mg doxycycline (equivalent to 20 mg of product)/ kg b.w. / day for, 5 days

9. ADVICE ON CORRECT ADMINISTRATION

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

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

To ensure a correct dosage body weight should be determined as accurately as possible.

The uptake of medicated water depends on the clinical condition 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.

Only sufficient medicated drinking water should be prepared to cover daily requirements.

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

Pigs:
Meat and offal: 6 days

Chickens:
Meat and offal: 6 days
Eggs: Not authorized for use in laying birds producing eggs for human consumption.

Turkeys
Meat and offal: 9 days
Eggs: Not authorized for use in laying 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 storage conditions.
Shelf-life after dilution in drinking water: 24 hours.
After first opening the immediate packaging, discard the unused veterinary medicinal product.

12. SPECIAL WARNINGS

Special precautions for use in animals
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.
Sick animals may have a reduced appetite and an altered drinking pattern and should, if necessary, be medicated parenterally.

Special precautions for use in animals
Avoid administration in oxidised drinking equipment.

Due to likely variability (time, geographical) in susceptibility of bacteria to doxycycline, bacteriological sampling and susceptibility testing are recommended.

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.

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.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
If you know you are allergic to the tetracycline class of antibiotics, special care should be taken when handling this product or the medicated solution.

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.

Use during pregnancy and lactation or lay:
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, foetotoxic, maternotoxic effects of doxycycline.
However, the safety of the veterinary medicinal product has not been established in pregnant or lactating sows.
The veterinary medicinal product should not be used during pregnancy or lactation

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. Do not administer together with antacids, kaolin and iron preparations as tetracyclines are bacteriostatic antimicrobials, do not administer in conjunction with bactericidal antibiotics like beta-lactames. 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 increases the action of anticoagulants.

Overdosage (symptoms, emergency procedures, antidotes)
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 no cause any adverse reaction.
In case of overdose treatment should be suspended and symptomatic treatment established.

Incompatibilities
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

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15. OTHER INFORMATION

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Batch number
EXP

Do not use after the expiry date which is stated on the label.

For animal treatment only. To be supplied only on veterinary prescription
Reg. nº.:

Bag of 1 Kg

Not all pack sizes may be marketed