

B. LABEL LEAFLET

PACKAGE LEAFLET FOR:

Doxycycline Calier 125 mg/g Premix for medicated feeding stuff for pigs

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 responsible for batch release:

Laboratorios Calier, S.A.
C/. Barcelonés, 26 (P.I. El Ramassar)
Les Franqueses del Vallès. Barcelona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxycycline Calier 125 mg/g Premix for medicated feeding stuff for pigs
Doxycycline hyclate

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

Each g contains:

Active substances:

Doxycycline (hyclate) 125 mg

Excipients:

Shelled almond flour.....167 mg

Yellowish-white granulated powder

4. INDICATION(S)

Treatment and metaphylaxis of clinical respiratory infections caused by *Actinobacillus pleuropneumoniae* susceptible to doxycycline.

The presence of the disease in the group/flock must be established before the product is used.

5. CONTRAINDICATIONS

Do not use in case of known hypersensitivity to the active substance or to any of the excipients.

Do not use in animals with hepatic dysfunction.

Do not use in breeding animals.

6. ADVERSE REACTIONS

As for all tetracyclines, allergic reactions and photosensitivity may occur.

Intestinal flora may be affected if treatment is very prolonged, and this may result in digestive disorder.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pig (pig for fattening)

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

In feed use.

Dosage:

10 - 12 mg doxycycline per kg of body weight daily, equivalent to 80 – 95 mg veterinary medicinal product /kg bw/day, for 8 days.

9. ADVICE ON CORRECT ADMINISTRATION

Administration:

Due to the intake of feed will vary depending on the clinical condition of the animals and the administration form, in order to obtain the correct dosage the concentration of doxycycline has to be adjusted accordingly. To calculate the dosage of the veterinary medicinal product, the following formula could be used as an example::

$$\frac{80 - 95 \text{ mg veterinary medicinal product per kg bw/ day} \times \text{Average pig body weight (kg)}}{\text{Average daily feed intake (kg/animal)}} = \text{mg veterinary medicinal product / per kg of feed}$$

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

The recommended incorporation rate in feed would be 2 kg of veterinary medicinal product per Tn of feed.

Pelletisation of medicated feed has to be carried out at a temperature not exceeding 80° C.

10. WITHDRAWAL PERIOD

Pigs (fattening pigs):

Meat: 5 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 25 °C.

Store in the original package in order to protect from light.

Shelf life after first opening the container: 4 months

Shelf life after incorporation into meal or pelleted feed: 4 months

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Use of the veterinary medicinal product should be based on susceptibility testing and take into account official and local antimicrobial policies.

Use of the product deviating from the instructions given in the SPC 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.

Feed intake is dependent on the clinical conditions of the animal. In case of insufficient feed ingestion, animals should be treated by parenteral route.

In order to avoid stress conditions, best handling measures should be taking into account, specially hygiene, ventilation and animals handling.

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

People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.

Handle this veterinary medicinal product with care to avoid inhalation of dust particles and skin and eye contact during the incorporation of the premix into feed, taking into account the following specific recommendations:

- Take adequate measures to avoid dust formation when incorporating the veterinary medicinal product into feed.
- Wear dust mask (in accordance with EN140FFP1), gloves, overalls and approved safety glasses.
- Direct contact of the veterinary medicinal product with the skin, eyes and mucous membranes should be avoided. In case of accidental exposure rinse abundantly with water.
- Do not smoke, eat or drink when handling the veterinary medicinal product.

In case of accidental ingestion or if you develop symptoms following exposure such as skin rash, you should, seek medical advice immediately and show the package leaflet or the label to the physician. Inflammation of the face, lips or eyes or respiratory difficulties are the most serious signs which require urgent medical attention.

Pregnancy:

Laboratory studies in laboratory animals (rats and rabbits) have not demonstrated toxic effects. The safety of the product has not been established in pregnant sows. The use is not recommended during pregnancy.

Lactation:

The safety of the product has not been established in lactating sows. The use is not recommended during lactation.

Fertility:

See section 5.

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+} , Al and Fe^{2+} because the formation of doxycycline complexes with these cations is possible. Do not administer together with kaolin and iron preparations.

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 PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

To be supplied only on veterinary prescription

Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

For animal treatment only.

Bags of 25 kg

Once opened use by...

Batch:

CAD:

Reg number