

PACKAGING, LABELLING AND PACKAGE INSERT

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

CALIERMUTIN 20 mg/g PREMIX (ES)

CALIERMUTIN 20 mg/g prè-mistura para alimento medicamentoso para suïnos e coelhos (PT)

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

Active Substance:

Tiamulin hydrogen fumarate 20 mg
(Equivalent to 16.2 mg of Tiamulin)

Excipients:

Excipient q.s. 1 g

Premix for medicated feeding stuff as granulated powder

4. INDICATION(S)

Pigs:

For the treatment and metaphylaxis, when the disease is present in the group, of swine dysentery caused by *Brachyspira hyodysenteriae* susceptible to tiamulin. The presence of the disease in the group must be established before the product is used.

Treatment and prevention of proliferative enteritis (ileitis), caused by *Lawsonia intracellularis*

Treatment of enzootic pneumonia induced by *M. hyopneumoniae*.

Rabbits:

Prevention and treatment of epizootic enterocolitis.

5. CONTRAINDICATIONS

Do not administer with ionophore polyether antibiotics as salinomycin, monensin or narasin.

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

6. ADVERSE REACTIONS

Occasionally cutaneous erythema and other hypersensitivity reactions may appear.

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

7. TARGET SPECIES

Pigs and rabbits.

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

Oral route mixed with feed

Pig:

- Treatment and metaphylaxis of swine dysentery induced by *B. hyodysenteriae* and treatment of enzootic pneumonia induced by *M. hyopneumoniae*.
The treatment dose is 8 mg of Tiamulin / kg bw/day administered in feed during 10-14 days.
- Treatment and prevention of ileitis caused by *Lawsonia intracellularis*.
The dose is 8 mg of Tiamulin / kg bw/day administered in feed during 14 days.

Posology of Caliermutin 20 mg/g Premix in feed may be established according to the following formula:

$$\text{mg of Caliermutin 20 mg/g premix / kg of feed} = \frac{(247 \text{ or } 494 \text{ mg of Caliermutin 20 mg/g Premix /kg bw. and day}) \times (\text{mean bodyweight of the animals to treat (Kg)})}{\text{mean of feed daily intake (Kg)}}$$

As a standard the incorporation rate in feed may be established in 5 Kg of Caliermutin 20 mg/g Premix /Tn of feed for prevention and 10 kg Caliermutin 20 mg/g premix for treatment.

Rabbits:

- Treatment and prevention of epizootic enterocolitis.
The dose of Tiamulin is 1.9 mg/ Kg.bw/day administered by feed. It is recommended to maintain this treatment from the weaning and during the four first weeks of fattening.

Posology of Caliermutin 20 mg/g premix in feed may be established according to the following formula:

$$\text{mg of Caliermutin 20 mg/g\% PREMIX / kg of feed} = \frac{(117,5 \text{ mg of Caliermutin 20 mg/g premix /kg bw. and day}) \times (\text{mean bodyweight of the animals to treat (Kg)})}{\text{mean of feed daily intake (Kg)}}$$

As a standard the incorporation rate in feed may be established in 2 Kg of Caliermutin 20 mg/g Premix /Tn of feed.

Due to the administration route and as the feed intake depends on the clinical condition of the animal, concentration of antibiotic will be fit considering feed daily intake in order to ensure a correct dosage.

9. ADVICE ON CORRECT ADMINISTRATION

In order to guarantee a homogeneous mixture, mix properly.

Do not administer with ionophore polyether antibiotics.

In case of any infective process, a bacteriological confirmation of the diagnosis is recommended, as well as a sensitivity test of the bacteria causing the process.

10. WITHDRAWAL PERIOD

Meat : Pigs: 5 days

Rabbits: 0 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

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

Shelf-life after incorporation into feed: 3 months.

Shelf-life after first opening the immediate packaging: the product should be immediately used.

12. SPECIAL WARNINGS

Special warnings for each target species

In pigs and rabbits do not administer with ionophore polyether antibiotics.

The uptake of medicated feed by animals can be altered as a consequence of illness.

In case of insufficient feed intake, animals should be treated parenterally.

Special precautions for use

Special precautions for use in animals

In pigs and rabbits do not administer with ionophore polyether antibiotics.

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

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

People with known hypersensitivity to tiamulin should handle the product with care. Tiamulin may cause irritation of the respiratory tract and eyes after its inhalation or contact.

Handle the product with care to avoid contact during incorporation of premix into feed, as well as when administering the medicated feed to animals, by taking specific precautions:

Avoid dust dissemination during the incorporation of the product into feed.

Wear a dust mask (in compliance with EN140FFP1), gloves, overalls, and approved safety glasses.

Avoid contact with eyes and if it occurs wash immediately with plenty of water.

Avoid contact with skin and if it occurs wash with water and soap.

Do not smoke, eat, or drink when handling the product

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Interaction with other medicinal products and other forms of interaction

Administration with ionophore polyether antibiotics in pigs may produce anorexia, diarrhoea, ataxia, lethargy, dyspnoea, myoglobinuria and death.

In rabbits administration of ionophore polyether with tiamulin may produce anorexia and gastroenteritis.

Overdose (symptoms, emergency procedures, antidotes), if necessary

In case of overdose, symptoms are transitory salivation, vomit and lethargy

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. Ask your veterinary surgeon 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

15. OTHER INFORMATION

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

Reg No.:

Bags of 25 kg

UNDER VETERINARY PRESCRIPTION

Batch:

Expires: