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.
Tel: 93 849 51 33
Fax: 93 840 13 98
e-mail: laboratorios@calier.es

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MACROMUTIN 125 mg/ml ORAL SOLUTION FOR POULTRY AND PIGS (ES)
CALIERMUTIN 125 mg/ml ORAL SOLUTION POULTRY AND PIGS (PT)

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

Each ml contains:

Active substance:
Tiamulin ..... 101.2 mg
Equivalent to Tiamulin hydrogen fumarate ..... 125.0 mg

Excipients:
Methyl parahydroxybenzoate (E219) ..... 0.9 mg
Propyl parahydroxybenzoate (E217) ..... 0.1 mg

4. INDICATION(S)

Poultry (Broilers, layer hens, breeder hens and turkeys):

Treatment and prevention of chronic respiratory disease (CRD) caused by strains sensitive to tiamulin: *Mycoplasma gallisepticum, Mycoplasma meleagridis*.

Porcine:

- Treatment of enzootic pneumonia caused by strains sensitive to tiamulin: *Mycoplasma hyopneumoniae, Mycoplasma hyorhinis*.
- Treatment of haemorrhagic dysentery caused or complicated by strains sensitive to tiamulin: *Brachyspira hyodysenteriae*

5. CONTRAINDICATIONS

Do not use the product with monovalent ionophore antibiotics, 7 days before, during and 7 days after the treatment of animals.

6. ADVERSE REACTIONS

In rare cases, hypersensitivity to tiamulin following oral administration has been reported, in terms of acute dermatitis with subcutaneous erythema and intense pruritus.

Adverse reactions are often mild and transient but in some cases they can be serious. If these side effects occur, stop treatment immediately and clean animals and facilities with water. Normally, animals recover fast thereafter. Symptomatic treatment such as electrolyte therapy and anti-inflammatory therapy may be useful.

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

7. TARGET SPECIES

Poultry (Broilers, layer hens, breeder hens and turkeys) and porcine.

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

Oral route in drinking water

Poultry (Broilers, laying hens, breeder hens and turkeys):

20 mg of tiamulin base/ kg b.w. per day (equivalent to 24.7 mg de tiamulin hydrogen fumarate / kg b.w./day), by oral route in drinking water, equivalent to 19.75 ml of product per 100 kg of body weight per day, for 3 to 5 days depending on the severity of the disease.

Posology of MACROMUTIN 125 mg/ml oral solution can be established according to the following formula:

ml MACROMUTIN 125 mg/ml oral solution /l water=
(0.1975 ml MACROMUTIN 125 mg/ml oral solution /kg b.w. / day) X (animals mean body weight (kg)) / mean water intake (l)

For a water consumption of 183.1 ml/kg b.w., this dose equals to 1.079 ml of MACROMUTIN 125 mg/ml oral solution /l of water. In order to respect the dosage and taking into account the real water consumption, incorporation rate can be increased, which would mean a higher concentration in water.

Porcine:

6.48-8.10 mg tiamulin base/ kg b.w. per day (equivalent to 8-10 mg of tiamulin hydrogen fumarate/ kg b.w./day) for 5 days by oral route in drinking water, equivalent to 6.4-8 ml of product per 100 kg of body weight per day, for 5 days.

Posology of MACROMUTIN 125 mg/ml oral solution can be established according to the following formula:

ml MACROMUTIN 125 mg/ml oral solution /l water=
(0.064-0.08 ml MACROMUTIN 125 mg/ml oral solution /kg b.w. / day) X (animals mean body weight (kg)) / mean water intake (l)

For a water consumption of 81 ml/kg b.w., this dose equals to 0.79 – 0.987 ml of MACROMUTIN 125 mg/ml ORAL SOLUTION /l of water. In order to respect the dosage and taking into account the real water consumption, incorporation rate can be increased, which would mean a higher concentration in water.

Medicated drinking water should be refreshed or replaced every 24 hours

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Meat and offal:

Porcine: 6 days
Broilers, laying hens and breeders: 6 days
Turkeys: 6 days
Eggs: zero 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 dilution or reconstitution according to directions: 24 hours.
After first opening the immediate packaging, discard the unused product.

12. SPECIAL WARNINGS

Special precautions for use in animals:

Use of the product should be based on susceptibility testing.
Strategic treatment should be limited to animals where tiamulin sensitive agents have been isolated in the farm. Long term or repeated use should be avoided by improving management practice and thorough cleansing and disinfection.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to Tiamulin should avoid any contact with the product.

- Avoid skin and mucous contact.
- Tiamulin can cause irritation of the respiratory tract and eyes after its inhalation or contact.
- The product should be carefully handled to avoid contact during its incorporation into drinking water.
- During product handling, use protective gloves, mask and glasses in accordance with the current normative.
- Precautions recommended to avoid a possible exposition are:
    - 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.

The safety of the veterinary medicinal product has not been established in pregnant or lactating sows. Use only accordingly to the benefit/risk assessment by the responsible veterinarian
See section Contra-Indications.

Interaction with other medicinal products and other forms of interaction:
Incompatibility with certain ionophore antibiotics (see section 5 contraindications) may occur. Following simultaneous administration symptoms of intoxication as growth depression, paralysis and death are possible.

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

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

Batch number

For veterinary use

To be supplied only on veterinary prescription
Administration under control or supervision of a veterinary surgeon

Reg. nº.:

Container of 1litre