

LABELLING AND PACKAGE LEAFLET

A. LABELLING

LABEL - PACKAGE LEAFLET

Sulfaprex 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:

LABORATORIOS CALIER, S.A.

C/ Barcelonès, 26 (Pla del Ramassà)

LES FRANQUESES DEL VALLÈS, (Barcelona)

SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sulfaprex Premix for medicated feeding stuff for pigs

(sulfadiazine + trimethoprim)

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

Each gram contains:

Sulfadiazine.....250 mg

Trimethoprim50 mg

Excipients:

Calcium carbonate

Yellowish-white granulated powder

4. INDICATION(S)

For the treatment of mastitis, metritis and agalaxia syndrome (MMA), atrophic rhinitis (when associated with *Bordetella bronchiseptica*) and diarrhoeas caused by strains of *E. coli* sensitive to sulfadiazine and trimethoprim.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to the active ingredients.

Do not use in animals with renal or hepatic insufficiency.

Do not use in animals with blood dyscrasias.

6. ADVERSE REACTIONS

Not known.

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

7. TARGET SPECIES

Pigs

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

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

The recommended dosage is 30 mg combined activity (25 mg sulfadiazine and 5 mg Trimethoprim) per kg bodyweight / day for 5 days. This is equivalent to 1 g of product per 10 Kg bodyweight/ day. This may be achieved by incorporating 2 Kg premix per tonne of feed (assuming a pig eats 5% of their bodyweight per day). The following table gives a guide to the appropriate feed inclusion rates according to the appetite of the pigs:

Daily feed intake per kg bodyweight (% bodyweight)	Dose: 30 mg/kg bodyweight/day
	Quantity of premix to be incorporated per tonne of feed
20 g/kg bw (2%)	5 kg
30 g/kg bw (3%)	3.3 kg
40 g/kg bw (4%)	2.5 kg
50 g/kg bw (5%)	2 kg

Do not pellet above 75°C.

9. ADVICE ON CORRECT ADMINISTRATION

Do not administrate to animals with known hypersensitivity to sulphonamides, or renal or hepatic insufficiency. It is essential the suitable ingestion of water.

10. WITHDRAWAL PERIOD

Meat and offal: 5 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Protect from light. Do not use after the expiry date stated on the label

Shelf-life after first opening the container: 3 months

Shelf-life after incorporation into meal or pelleted feed: 55 days

12. SPECIAL WARNING(S)

Special warnings for each target species

Bacteriological aetiology should be confirmed. Whenever possible sulfadiazine and trimethoprim association should only be used based on susceptibility testing.

The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of antimicrobial should be adjusted accordingly and water consume should be guaranteed.

In case the correct dosage could not be ensured by oral route, treat parenterally using an appropriate injectable product.

Special precautions for use in animals

To avoid the possibility of crystalluria, adequate water intake is essential. Particular care is needed with animals suffering from renal damage.

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

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

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

Avoid contact with skin and eyes. In case of contact, wash the exposed area immediately with water.

Personal protective equipment consisting of mask and gloves should be worn when handling the veterinary medicinal product.

Wash hands after use.

If symptoms such as rash appear after exposure, seek medical attention and present these warnings. Swelling of face, lips or eyes, and difficulty breathing are serious signs that require urgent medical attention.

Do not smoke, eat or drink while handling this product.

Use during pregnancy and lactation

The product can be used during lactation.

Interaction with other medicaments and other forms of interaction:

Do not administer with PABA and derivatives.

Do not administer with oral anticoagulants or urinary acidifier.

Overdose (symptoms, emergency procedures, antidotes):

The product has been shown to be well tolerated at up to two times the recommended dosage in pigs.

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

To be supplied only on veterinary prescription

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