LABELLING AND PACKAGE LEAFLET

A. LABELLING

LABEL -PACKAGE LEAFLET

SulfaprexPremix 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/ Barcelonès, 26 (Pla del Ramassà)
LES FRANQUESES DEL VALLÈS, (Barcelona)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sulfaprex250/50 mg/g Premix for medicated feeding stuff for pigs

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

Each gram contains:

Active substances:
Sulfadiazine.....250 mg
Trimethoprim .....50 mg

Excipients:
Calcium carbonate
Other excipients, q.s.

Yellowish-white granulated powder

4. INDICATION(S)

For the treatment of mastitis, metritis and agalaxiasyndrome (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 cases ofhypersensitivity to the active substances, to dihydrofolate reductase inhibitors or to any of the excipients.
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 sideeffects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs

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

In-feed use.

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 for 5 days.

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

Due to the administration form and to the fact that feed consumption depend on the clinical condition of the animal, in order to assure a correct dosing, the antimicrobial concentration will be adjusted taking into account the daily consumption of feed. For example, the following formula may be used to calculate the medicinal product dose:

$$\frac{\text{100 mg Sulfaprex/ kg w./day} \times \text{Meanweight of animals to be treated (kg)}}{\text{Meandailyfeedintakeby animal (kg)}} = \text{Mg of Sulfaprex/ kg of feed}$$

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.

Do not pellet above 75ºC.

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 sightand reachof 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

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 consumptionshould be guaranteed.

Animals with reduced feed intake and/or disturbed general condition have to be treated parenterally.

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 of the bacteria isolated from the animal. If it is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

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

For animal treatment only. To be supplied only on veterinary prescription
Consideration should be given to official guidance on the incorporation of medical premixes in final feeds.
Pack size:
Bags of 25 kg
EXP {month/year}
Once opened use by…

MARKETING AUTHORISATION NUMBER(S)

<Batch><Lot><BN> {number}