SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT:

Sulfaprex 250/50 mg/gPremix for medicated feeding stuff for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each gram contains:

Active substances:

Sulfadiazine.....250 mg

Trimethoprim .....50 mg

Excipients:

Calcium carbonate

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM:

Premix for medicated feeding stuff.

Yellowish-white granulated powder

4. CLINICAL PARTICULARS:

4.1 Target species:

Pigs

4.2 Indications for use, specifying target species:

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

4.3 Contraindications:

Do not use in cases of hypersensitivity 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.

4.4 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.

4.5 Special precautions for use

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 this 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.

4.6 Adverse reactions (frequency and seriousness):

Not known.

4.7 Use during pregnancy and lactation

The product can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction:

Do not administer with PABA and derivatives.

Do not administer with oral anticoagulants or urinary acidifier.

4.9 Amounts to be administered and administration route:

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:

$$\frac{\text{100 mg Sulfaprex/ kg w./day} \times \text{Mean weight of animals to be treated (kg)}}{\text{Mean daily feed intake by animal (kg)}} = \text{Mg of Sulfaprex/ kg of feed}$$

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.

4.10 Overdose (symptoms, emergency procedures, antidotes):

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

4. 11 Withdrawal period:

Meat and offal: 5 days.

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinfectives for systemic use, combinations of sulfonamides and trimethoprim, incl. derivates
ATCVet Code: QJ01EW10

5.1 Pharmacodynamic properties

The product contains the antimicrobial combination of sulfadiazine and trimethoprim in a 5:1 ratio as premix for medicated feeding stuff form.

Sulfadiazine is a bacteriostatic antibiotic that acts blocking synthesis of folic acid carriers of monocarbonated unities, essential to acid nucleic synthesis. This action is consequence of structural analogy between sulfadiazine and paraminobenzoic acid molecules.

The two compounds act sequentially on the same bacterial enzymatic pathway leading to the synthesis of tetrahydrofolic acid, a vital step in bacterial DNA synthesis. This action results in a synergistic antibacterial effect which has been demonstrated both *in vitro* and *in vivo*.

5.2. Pharmacokinetic particulars

The particular kinetics of sulfadiazine and trimethoprim lend this combination to being the most appropriate potentiated sulfonamide preparation available for pigs. Bioavailability is high and elimination half lives for the two active substances are virtually the same. Distribution of both active ingredients is excellent especially trimethoprim which has a relatively large volume of distribution.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium carbonate
Paraffin liquid
Hydrophobic colloidal silica

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products..

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening the immediate packaging: 3 month
Shelf-life after incorporation into meal or pelleted feed: 55 days

6.4 Special precautions for storage:

Protect from light.

6.5 Nature and composition of immediate packaging:

25 kg multi-layer paper bag with internal low density polyethylene bag.
Bags with five layers ordered from interior to exterior:

1. Low density polyethylene sheet
2. Kraft semiextensible
3. Kraft semiextensible
4. Kraft semiextensible
5. Semiextensible Blank

Pack size:

Bag of 25 kg.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

LABORATORIOS CALIER, S.A.
C/ Barcelonès, 26 (Pla del Ramassà)
LES FRANQUESES DEL VALLÈS, (Barcelona)
SPAIN

8. MARKETING AUTHORISATION NUMBER (S)

9. DATE OF THE FIRST AUTHORISATION /RENEWAL OF THE AUTHORISATION

<Date of first authorization><{DD/MM/YYYY}><{DD/month/YYYY}>
<Date of last renewal><{DD/MM/YYYY}><{DD/month/YYYY}>

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription.

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