

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sulfaprex 250 mg/g + 50 mg/g premix for medicated feeding stuff for pigs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

### Active substances:

Sulfadiazine..... 250 mg

Trimethoprim ..... 50 mg

### Excipients:

Qualitative composition of excipients and other constituents
Liquid paraffin
Anhydrous colloidal silica
Calcium carbonate

Yellowish-white granulated powder.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Pigs.

### 3.2 Indications for use for each 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.

### 3.3 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.

### 3.4 Special warnings

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 consumption should be guaranteed.

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

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

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

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

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.

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

Wash hands after use.

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

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 veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

### **3.6 Adverse events**

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the immediate packaging for respective contact details.

### **3.7 Use during pregnancy, lactation or lay**

Lactation:

The veterinary medicinal product can be used during lactation.

### **3.8 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.

### **3.9 Administration routes and dosage**

In-feed use.

Dosage: 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 veterinary medicinal product per 10 Kg bodyweight/ day for 5 days.

To ensure a correct dosage, body weight should be determined as accurately as possible. The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of sulfadiazine and trimethoprim may need to be adjusted accordingly.

**Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:**

$$\text{mg of veterinary medicinal product / kg of feed} = \frac{100 \text{ mg of veterinary medicinal product /kg b.w./per day} \times \text{average body weight (kg) of animals to be treated}}{\text{mean daily feed intake of animals (kg)}}$$

Do not pellet above 75°C.

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

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

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

This veterinary medicinal product is intended to be used for the preparation of medicated feed.

### **3.12 Withdrawal periods**

Meat and offal: 5 days.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code: QJ01EW10**

### **4.2 Pharmacodynamics**

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*.

### **4.3 Pharmacokinetics**

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.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

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

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 3 months.

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

### **5.3 Special precautions for storage**

Protect from light.

### **5.4 Nature and composition of immediate packaging**

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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## **6. NAME OF THE MARKETING AUTHORISATION HOLDER**

LABORATORIOS CALIER, S.A.

## **7. MARKETING AUTHORISATION NUMBER(S)**

VPA10665/005/001

**8. DATE OF FIRST AUTHORISATION**

11/01/2013

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

29/01/2026

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).