ANNEX III

LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

{BAG OF 25 kg}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. 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. PACKAGE SIZE

25 kg

4. TARGET SPECIES

Pigs and sheep (pre-ruminant).

5. INDICATIONS FOR USE

Indications for use

<u>Pigs</u>: For the treatment of respiratory infections caused by strains of *Pasteurella multocida*, *Actinobacillus pleuropneumoniae*, *Haemophilus parasuis* y *Streptococcus suis* sensitive to sulfadiazine and trimethoprim.

<u>Sheep (pre-ruminant):</u> For the treatment of respiratory infections caused by strains of *Pasteurella multocida* sensitive to sulfadiazine and trimethoprim.

6. CONTRAINDICATIONS

Contraindications

Do not use 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.

7. SPECIAL WARNINGS

Special warnings

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

Special precautions for safe use in the target species:
Whenever possible sulfadiazine and trimethoprim association should only be used based on susceptibility testing.
Use of the 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 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.
Handle the veterinary medicinal product with care in order to avoid its contact during feed manufacturing, as well as during medicated feed administration to animals.
Take the suitable measures to avoid dust dissemination during medicated feed manufacture.
Personal protective equipment consisting of mask (in accordance with EN140FFP1), gloves, work clothes and safety glasses should be worn when handling the veterinary medicinal product.
Avoid contact with skin and eyes. In case of contact, wash the exposed area immediately with water.
Do not smoke, eat or drink while handling this veterinary medicinal product.
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.

Pregnancy:
Do not use during the whole pregnancy or in neonates.

Lactation:
Do not administer to lactating females whose milk is destined for human consumption.

Interaction with other medicinal products and other forms of interaction:

Do not administer simultaneously with acid para-aminobenzoic (PABA) and derivatives (procaine, benzocaine, tetracaine,…) and in general do not administer with substances or feed that have PABA and/or folic acid.
Do not administer with oral anticoagulants or urinary acidifier.

Overdose:
In case of overdose, the following signs can be observed:
- Digestive signs: nauseas, vomiting, anorexia, diarrhoea.
- Urinary signs: crystaluria.
- Hematopoietic alterations, such as thrombocytopenia or leukopenia.

In case of severe overdose, withdraw the treatment, give plenty of water and administer folic acid.

Special restrictions for use and special conditions for use:
This veterinary medicinal product is intended to be used for the preparation of medicated feed.
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Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

8. ADVERSE EVENTS

Adverse events

Pigs and sheep (pre-ruminant):

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Crystalluria, haematuria Urinary tract obstruction Allergic reaction[1] Nausea, vomiting, diarrhoea

[1] With possible cutaneous manifestations.
If any of these manifestations appear, discontinue treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details on this label, or via your national reporting system:

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

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 product per 10 Kg bodyweight/ day.

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 a correct dosage, the concentration of sulfadiazine and trimethoprim may need to be adjusted. 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:

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

Method of administration: to mix with feed once it is manufactured. In the granulation process is recommended to prepare the mix with vapour between 5 -10 minutes at a temperature not exceeding 75ºC.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

11. WITHDRAWAL PERIODS

Withdrawal periods

Withdrawals periods:
Pigs:

- Meat and offal: 3 days.

Sheep (pre-ruminant):

- Meat and offal: 4 days.
- Milk: Not authorized for use in animals producing milk for human consumption.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack size:
Bag of 25 kg

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{MM/YYYY}

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

17. CONTACT DETAILS

Contact details

Marketing authorisation holder <,> <and> <manufacturer responsible for batch release> <and contact details to report suspected adverse events>:

<Local representatives <and contact details to report suspected adverse events>:>

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>

18. OTHER INFORMATION

<Other information>

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use by …

Shelf life after first opening the immediate packaging: 3 months.
Shelf life after incorporation into meal or pelleted feed for pigs: 55 days.
Shelf life after incorporation into meal or pelleted feed for pre-ruminant sheep: 50 days.

21. BATCH NUMBER

Lot {number}