1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sulfoprim 150 mg/g Premix for medicated feeding stuff

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each kg contains

Active substances:

Sulphadiazine 125 g
Trimethoprim 25 g

Excipients:

Qualitative composition of excipients and other constituents
Soya bean meal
Medium chain triglyceride

A pale brown uniform meal mix.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

For use in the treatment of diseases caused by bacteria sensitive to potentiated sulphonamide preparations.

3.3 Contraindications

This veterinary medicinal product is not recommended for use with any other premix or oral medication.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal 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:

Personal protective equipment consisting of a dust mask complying with BS2091 or BS6016 and impervious gloves should be worn when handling the 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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

This veterinary medicinal product is not recommended for use with any other premix or oral medication.

3.9 Administration routes and dosage

In-feed use.
For oral administration after incorporation into complete feed. The recommended therapeutic dose is 15 mg per kg bodyweight daily. To ensure a correct dosage, body weight should be determined as accurately as possible.

To achieve this dose, the veterinary medicinal product should be mixed into feed at the following inclusion rates:

Growing Pigs

Age of Pig (weeks-kg)	**Average Feed Intake-kg feed/day**	**Inclusion rate**
8 weeks (20 kg bodyweight)	1 kg	2 kg per tonne
12 weeks (30 kg bodyweight)	1.5 kg	2 kg per tonne
14 weeks (45 kg bodyweight)	2.0 kg	2 kg per tonne
16 weeks (60 kg bodyweight)	2.5 kg	2 kg per tonne

Treatment should be continued for a period of five days.

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

None.

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

Not applicable.

3.12 Withdrawal periods

Meat and offal: 10 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QJ01EW10

4.2 Pharmacodynamics

The veterinary medicinal product is used for the treatment of bacterial infections in pigs which are sensitive to potentiated sulphonamides.

Sulphadiazine

This sulphonamide is one of the more active members of the group and has been used with trimethoprim at the same ratio in a number of products.

Trimethoprim

Trimethoprim is widely used in human and veterinary medicine to potentiate sulphonamides of which a number may be used. The usual ratio of the combination for therapy is 1:5, trimethoprim : sulphonamide for most veterinary medicinal products.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after incorporation into meal or pelleted feed: 4 weeks.

5.3 Special precautions for storage

Do not store above 25 °C.
Store in a dry place.
Protect from light.

5.4 Nature and composition of immediate packaging

Primary packaging: A 20 kg LDPE bag or 10 x 2 kg LDPE bags within a 20 kg LDPE bag.
Secondary packaging: 20 kg triple layered paper bags.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Univet Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10990/033/001

8. DATE OF FIRST AUTHORISATION

01/05/1998

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

26/06/2026

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).