Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Sulfoprim 21% Premix for Medicated Feed

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each kg of product contains:

Active substances

Sulphadiazine	178.40 g
Trimethoprim	35.60 g

Excipients

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Premix for medicated feed

A pale brown, uniform, meal-like mix

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active substances.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

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

A dust mask complying with BS2091 or BS6016 must be worn when mixing the product into the feed.
Wear impervious gloves when handling this product.
Wash all exposed skin after use of this product.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

This product is safe for use in pregnant sows.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

For oral administration after incorporation into complete feed.

Pigs:
The recommended therapeutic dose is 30 mg of combined actives per kg bodyweight daily. To achieve this dose, the product should be mixed into feed at the following inclusion rates to provide approximately 25 $mg.kg^{-1}$ bodyweight Sulphadiazine and 5 $mg.kg^{-1}$ bodyweight Trimethoprim.

Age of Pig	*Average Feed*	*Inclusion*
(Weeks-kg)	*Intake - kg*	*feed/day*
8 weeks (20 kg bodyweight)	1.0 kg	2.8 kg per tonne
12 weeks (30 kg bodyweight)	1.5 kg	2.8 kg per tonne
14 weeks (45 kg bodyweight)	2.0 kg	2.8 kg per tonne
16 weeks (60 kg bodyweight)	2.5 kg	2.8 kg per tonne

Treatment should be continued for a period of five days.

To ensure thorough dispersion of the product it should be first mixed with 20 kg of feed ingredients before incorporation into a suitable final feed.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

None known

4.11 Withdrawal Period(s)

Pigs must not be slaughtered for human consumption during treatment.
Pigs may be slaughtered for human consumption only after 10 days after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, combinations of sulphonamides and trimethoprim
ATCvet Code: QJ01EW10

5.1 Pharmacodynamic properties

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 products.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Medium chain triglyceride
Soya meal

6.2 Incompatibilities

None known

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after incorporation into feed: 4 weeks

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.

6.5 Nature and composition of immediate packaging

A pale brown meal mix in LDPE lined 20 kg triple-layered paper bags.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Univet Limited
Tullyvin
Cootehill
County Cavan

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10990/025/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1989
Date of last renewal: 30th September 2009

10 DATE OF REVISION OF THE TEXT

August 2015