Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Sulfoprim 15% Premix for Medicated Feed.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each kg contains	
Active Ingredients	
Sulphadiazine	125 g
Trimethoprim	25 g
Excipient	
Soya bean meal	

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Premix for Medicated Feed.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

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

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. The recommended therapeutic dose is 15 mg of combined actives per kg bodyweight daily. To ensure a correct dosage, body weight should be determinated as accurately as possible.

To achieve this dose, *Sulfoprim 15% Meal Mix* 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.

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

None.

4.11 Withdrawal Period(s)

Meat and offal: 10 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, sulfadiazine and trimethoprin.

ATCvet code QJ01EW10

5.1 Pharmacodynamic properties

Sulfoprim 15% Premix for Medicated Feed 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 products.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Medium chain triglyceride
Soya bean 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 meal or pelleted feed:
4 weeks.

6.4 Special precautions for storage

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

6.5 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.

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

Unused product and waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Univet Limited
Tullyvin
Cootehill
Co Cavan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10990/033/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st May 1998
Date of last renewal: 30th April 2008

10 DATE OF REVISION OF THE TEXT

August 2015