

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Uniprim 150 Premix for medicated feed

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each kg contains :

### Active ingredients

Sulfadiazine	125 g
Trimethoprim	25 g

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Premix for medicated feed.

Light grey powder for incorporation into feed.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Pigs and non-laying chickens

### 4.2 Indications for use, specifying the target species

For use in the prevention and treatment of diseases in pigs and non-laying chickens caused by bacteria sensitive to the combination of sulfadiazine and trimethoprim.

#### **Growing pigs:**

- i) for the treatment of streptococcal disease, e.g. meningitis, caused by sensitive strains of *Streptococcus* spp.
- ii) for the treatment of atrophic rhinitis where associated with sensitive *Bordetella bronchiseptica*.
- iii) for the treatment of diarrhoea caused by sensitive *Escherichia coli*.

#### **Sows:**

For the prevention and treatment of mastitis, metritis and agalactia (MMA) syndrome of sensitive bacterial origin.

#### **Non-laying chickens:**

For use in prevention and treatment of septicaemic infections caused by bacteria sensitive to the combination sulfadiazine and trimethoprim. Bacteria which may be sensitive include *E.coli*, *Salmonella* spp. and *Pasteurella multocida*.

### 4.3 Contraindications

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

Do not use in animals with severe liver parenchymal damage.

Do not administer to birds producing eggs for human consumption.

### 4.4 Special warnings for each target species

The uptake of medication by animals can be altered as a consequence of illness. For animals with a reduced feed intake, treat parenterally using an appropriate injectable product.

### 4.5 Special precautions for use

#### Special precaution(s) for use in animals

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

Use of the product should be based on susceptibility testing and take into account official and local antimicrobial procedures.

#### Special precautions to be taken by the person administering the veterinary medicinal product to animals

Operators should take necessary precautions to avoid contact with the preparation. It is recommended that dust masks and other protective clothing are worn during the handling and mixing of this product. Hands and exposed skin should be washed thoroughly at the end of the operation.

### 4.6 Adverse reactions (frequency and seriousness)

None.

### 4.7 Use during pregnancy, lactation or lay

Potentiated sulfonamides are an established treatment of MMA syndrome in sows.

### 4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

The product should be incorporated in animal feedingstuffs at the rates given below, mixed thoroughly and administered for the periods specified.

DOSAGE:

Growing pigs and sows:

The recommended daily dosage is 15-30 mg combined activity per kg bodyweight; for the treatment of streptococcal disease and *E.coli* diarrhoea, the dosage should be 30 mg/kg.

The following table gives a guide to the appropriate feed inclusion rates of Uniprim 150 according to dosage required and appetite of pigs:

Daily feed intake vs. pig bodyweight (= % of bwt)	15 mg/kg Inclusion rate of Uniprim 150 per 1000 kg feed	30 mg/kg
20 g/kg (=2%)	5 kg	10 kg
30 g/kg (=3%)	3.3 kg	6.6 kg
40 g/kg (=4%)	2.5 kg	5 kg
50 g/kg (=5%)	2 kg	4 kg
60 g/kg (=6%)	1.6 kg	3.2 kg
70 g/kg (=7%)	1.4 kg	2.8 kg

Non-laying chickens:

The recommended daily dosage is 25-30 mg combined activity per kg bodyweight. This is equivalent to 2 kg Uniprim 150 per 1000 kg feed.

DOSAGE SCHEDULE:

For growing pigs, the medication should be given daily for 5 days.

For sows, the medication should be given daily for 3 days prior to parturition and continued for 2 days after parturition.

For non-laying chickens, the medication should be given daily for 10 days.

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

The product has been shown to be well tolerated at up to two times the recommended dosage in pigs and up to six times the recommended dosage in chickens. The wide margin of safety for potentiated sulfonamides is well established.

4.11 Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment.

**Pigs** intended for human consumption may only be slaughtered from 5 days after the last treatment.

**Non-laying chickens** intended for human consumption may only be slaughtered from 24 hours after the last treatment.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QJ01EW10

Pharmacotherapeutic Group: Sulfadiazine and trimethoprim

### 5.1 Pharmacodynamic properties

The product contains the antimicrobial combination of sulfadiazine and trimethoprim in a 5 : 1 ratio. It is intended for medication of feed for the therapy of diseases in pigs and non-laying chickens caused by organisms sensitive to the combination.

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*.

The particular kinetics of sulfadiazine and trimethoprim lend this combination to being the most appropriate potentiated sulfonamide preparation available for pigs and poultry. Bioavailability is high and elimination half lives for the two active substances are virtually the same i.e. they have parallel depletion rates, thereby maintaining a consistent antibiotic ratio in the tissues and fluids of the animal. Distribution of both active ingredients is excellent especially trimethoprim which has a relatively large volume of distribution.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Limestone powder

Soya bran

### 6.2 Incompatibilities

None known.

### 6.3 Shelf-life

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

The product remains stable in non-pelleted and pelleted feed for up to 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

Polyester/aluminium foil/polyethylene bags (heat sealed) containing 2 or 5 kg light grey powder.

Quadruple walled paper bags (stitch sealed) with second and inner ply polyethylene coated or polyethylene lined containing 10, 12 or 25 kg light grey powder.

Not all pack sizes may be marketed.

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

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

## **7 MARKETING AUTHORISATION HOLDER**

Pfizer Healthcare Ireland  
Trading as:  
Pfizer Healthcare Ireland  
Ringaskiddy  
Co. Cork

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10019/099/001

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

19th April 2008

## **10 DATE OF REVISION OF THE TEXT**

14th April 2009