Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Aurofac Granular 250 mg/g Premix for medicated feedingstuff for pigs and chickens

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of premix contains:

Active substance(s): Chlortetracycline hydrochloride 250 mg/g

Excipients:
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Premix for medicated feeding stuff.
Granular yellow powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs and chickens.

4.2 Indications for use, specifying the target species

Pigs
As an aid in the treatment and control of swine respiratory disease complex associated with chlortetracycline-sensitive organisms. The following pathogens in pigs are generally considered as sensitive to chlortetracycline (refer to section 4.5.i): *Actinobacillus pleuropneumoniae, Bordetella bronchiseptica, Erysipelothrix rhusiopathiae, Escherichia coli, Haemophilus parasuis, Leptospira* spp., *Lawsonia intracellularis, Mycoplasma* spp, *Pasteurella multocida, Streptococcus suis.*

Chickens
As an aid in the treatment and control of respiratory and systemic infections associated with chlortetracycline-sensitive organisms. The following pathogens in chickens are generally considered as sensitive to chlortetracycline (refer to section 4.5.i): *Escherichia coli, Mycoplasma gallisepticum, Mycoplasma synoviae, Ornithobacterium rhinotracheale, Pasteurella multocida.*

4.3 Contraindications

Do not use in adult ruminants.
Do not use in animals where resistance to the active substance is known to occur.
Do not use in case of hypersensitivity to the active substance.

4.4 Special warnings for each target species

Pigs: Use of the product during the period of tooth development may lead to tooth discolouration.

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. Official, national and regional antimicrobial policies should be taken into account when the product is used.

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

Do not handle this product if you know that you are sensitized, or if you have been advised not to work with such preparations. Do not smoke, eat or drink while handling the product. Avoid contact with skin and eyes. If contact takes place, wash with plenty of clear water. The product may cause irritation to skin and eyes. Handle the product with great care to avoid exposure, taking all recommended precautions. Personal protective equipment (gloves, overalls and approved safety glasses) should be worn. If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention. Wash hands after use and before meals.

4.6 Adverse reactions (frequency and seriousness)

The product is of low toxicity and side effects are rarely encountered. The most frequent side effect is gastrointestinal disturbance such as diarrhoea. If suspected adverse reactions do occur, treatment should be discontinued immediately.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals have not produced any evidence of adverse effects during pregnancy. Safety of the veterinary medicinal product has not been investigated in sows during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer together with bactericidal antibiotics such as the beta-lactam antibiotics (penicillins and cefalosporins), as chlortetracycline may reduce their antibacterial activity.

4.9 Amounts to be administered and administration route

The recommended dosage rates are:

Pigs	10-20 mg/kg bodyweight daily
Chickens - broilers	20-30 mg/kg bodyweight daily
Chickens – laying hen	20-25 mg/kg bodyweight daily

For the preparation of the medicated feed, the incorporation rate of product per tonne of feed will vary depending on the body weight of the animals/birds to be treated and their actual daily intake of feed.

To help obtain uniform dispersion, first thoroughly mix the required amount of the product with 10 times its weight of feed ingredient before blending into the final mix. The medicated feed should be supplied to the affected pen(s) or group(s) of pigs or chickens.

Treatment should be continued for a period of five to seven days.
During the treatment period, only feed medicated should be supplied.

In case of disease accompanied by decreased appetite, parenteral treatment should be initiated.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

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

Chlortetracycline is of low toxicity and there is a wide safety margin at the recommended dosage. On rare occasions overdosage may cause diarrhoea and over growth of yeast and fungi. Under such conditions, withdraw medication and apply appropriate treatment.

4.11 Withdrawal Period(s)

Meat and offal:
Pigs: 10 days
Chickens: 2 days

Eggs:
Chickens: 4 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic class: Antibacterials for systemic use - tetracyclines
ATCvet code: QJ01AA03

5.1 Pharmacodynamic properties

Chlortetracycline is a broad spectrum antibiotic of the tetracycline group.
Tetracyclines act by inhibiting protein synthesis, binding reversibly to receptors of the 30S ribosomal subunit of susceptible microbes. The initial binding blocks the later binding of aminoacyl-tRNA to the acceptor site on the mRNA-ribosomal complex, preventing the addition of new amino acids to new peptide chains, inhibiting protein synthesis. Tetracyclines enter the micro-organism by both passive diffusion and active transport mechanisms. Susceptible micro-organisms will concentrate the antibiotic, while resistant strains carry R-factors (typically plasmid borne) which either inhibit the uptake of the drug or causes efflux (pumping) out of the cell. Alternatively, ribosomes may be modified by mutation to prevent tetracycline activity (target modification).

Tetracyclines can also inhibit protein synthesis in the host, but are less likely to reach the concentration required because eukaryotic cells do not have a tetracycline uptake mechanism. At recommended dosages it has no pharmacological effects on cardio-vascular, nervous or other body systems.

Resistance among target pathogens may develop fast due to horizontal transmission (plasmids). Regional differences in the resistance pattern are present. A strain which is resistant to a tetracycline will also be resistant to other members of the class of tetracyclines.

The Clinical and Laboratory Standards Institute breakpoints established for tetracyclines are as follows:

For porcine and poultry strains:
Escherichia coli: S ≤ 4; I – 8; R≥ 16 µg/ml;
For porcine strains:
Streptococcus suis: S ≤ 0.5; I – 1; R≥ 2 µg/ml;
Pasteurella multocida: S ≤ 0.5; I – 1; R≥ 2 µg/ml;
Actinobacillus pleuropneumoniae: S ≤ 0.5; I – 1; R≥ 2 µg/ml.

5.2 Pharmacokinetic properties

When dosed orally it is absorbed into the blood stream, achieving effective concentrations in various tissues including lungs and other respiratory tissues. It is excreted in urine and faeces.
In pigs a dose of 20 mg/kg BW will provide a C_{max} of on average 1.5µg/ml in the blood with a T_{max} of ca.4 h after start of feeding and with a clearance $T_{½}$ of ca 12 h after reaching T_{max}.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carmellose sodium
Calcium sulfate dihydrate

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening the immediate packaging: 14 days
Shelf life after incorporation into meal or pelleted feed:
Stable in mash feed for up to 3 months.
Stable in pelleted feed for up to 3 weeks.

6.4 Special precautions for storage

Store apart from animal feeding stuffs.
Keep the bag tightly closed after use.

6.5 Nature and composition of immediate packaging

Polyethylene bags containing 2 kg, 3 kg, 4.8 kg, 6.4 kg, 8 kg, 9 kg, 12 kg, 16 kg, 20 kg, 25 kg.
Cardboard cartons containing 8 x 3 kg and 12 x 2 kg

Not all pack sizes may be marketed.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A,
2nd Floor
Building 10
Cherrywood Business Park
Co. Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10387/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st April 2011
Date of last renewal: 9th October 2015

10 DATE OF REVISION OF THE TEXT

March 2017