1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aurofac® Granular 250 mg/g Premix for medicated feeding stuff for pigs and chickens [IE, PT, SI]
Aurofac® 250 mg/g premezcla medicamentosa para porcino y aves [ES]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:

Chlortetracycline hydrochloride 250 mg/g

Excipients:

Qualitative composition of excipients and other constituents
Carmellose sodium
Calcium sulfate dihydrate

Premix for medicated feeding stuff.
Granular yellow powder.

3. CLINICAL INFORMATION

3.1 Target species

Pigs and chickens

3.2 Indications for use for each 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 3.5): *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 3.5): *Escherichia coli*, *Mycoplasma gallisepticum*, *Mycoplasma synoviae*, *Ornithobacterium rhinotracheale*, *Pasteurella multocida*.

3.3 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 cases of hypersensitivity to the active substance.

3.4 Special warnings

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

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. 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:
People with known hypersensitivity to chlortetracycline hydrochloride, or who have been advised not to work with such preparations, should avoid contact with the veterinary medicinal product. Avoid contact with the skin and eyes as the product may cause irritation. Personal protective equipment consisting of gloves, overalls and approved safety glasses should be worn when handling the veterinary medicinal product. In case of accidental spillage onto skin, wash with plenty of clear water. If you develop symptoms following exposure, such as skin rash, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention. Do not smoke, eat or drink while handling the product. Wash hands after use and before meals.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Pigs and chickens:

Rare (1 to 10 animals / 10,000 animals treated):	Gastrointestinal disorders*

*such as diarrhoea.
If suspected adverse reactions do occur, treatment should be discontinued immediately.

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 its local representative or the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
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.

3.8 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.

3.9 Administration routes and dosage

The recommended dosage rates are:

Pigs	10-20 mg/kg bodyweight daily
Chickens - broilers	20-30 mg/kg bodyweight daily
Chickens – laying hens	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.

The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of chlortetracycline hydrochloride may need to be adjusted accordingly.

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.

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

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.

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

This veterinary medicinal product is intended to be used for the preparation of medicated feed.

3.12 Withdrawal periods

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

Eggs:
Chickens: 4 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01AA03

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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 1.5 µg/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}.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

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

5.4 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.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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

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).