SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aurofac Granular 100 mg/g Premix for Medicated Feeding Stuff

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:	Chlortetracycline hydrochloride	100 mg/g
Carrier:	Calcium sulphate dihydrate	

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff

The product is a premix consisting of yellow free flowing granules

4. CLINICAL PARTICULARS

4.1 Target species

Pigs, chickens, turkeys, ducks

4.2 Indications for use, specifying the target species

For treatment and control of respiratory and systemic infections associated with organisms sensitive to chlortetracycline.

4.3 Contraindications

Do not use in ruminants

4.4 Special warnings

None

4.5 Special precautions for use

i. Special precautions for use in animals

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

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

If you know you are hypersensitive (allergic) to chlortetracycline, do not handle the product.
When handling this product, inhalation of the dust must be avoided by wearing a disposable half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143.
Avoid contact with skin and eyes. Gloves should be worn whilst handling this product. If contact with skin or eyes occurs, wash area immediately with clean fresh water. If irritation persists seek medical attention.
Do not eat, drink or smoke whilst handling the product. Hands and exposed skin should be washed thoroughly after use.

4.6 Adverse reactions (frequency and seriousness)

The product is of low toxicity and side effects are rarely encountered. If suspected adverse reactions occur, treatment should be discontinued immediately.

4.7 Use during pregnancy, lactation or lay

No problems known

4.8 Interaction with other medicinal products and other forms of interaction

Chlortetracycline is sometimes used in association with other antimicrobials, notably sulphadimidine, penicillin and neomycin. There are no known adverse reactions with these or any other substances.

4.9 Amounts to be administered and administration route

The recommended dose rates are as follows:

Pigs:	10–20 mg/kg bodyweight daily
Chickens:	20-30 mg/kg bodyweight daily
Turkeys:	10-30 mg/kg bodyweight daily
Ducks:	10-30 mg/kg bodyweight daily

These dose rates can usually be achieved by mixing 3.0 kg of Aurofac Granular 100 mg/g Premix for Medicated Feeding Stuff per tonne of complete feed to give a concentration of 300 ppm chlortetracycline hydrochloride. However, the correct incorporation rate should always be calculated based on the feed consumption rates of the animals to be treated.
The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of chlortetracycline has to be adjusted accordingly.

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

Aurofac Granular 100 mg/g Premix for Medicated Feeding Stuff can be incorporated in pelleted feed preconditioned at temperatures up to 70°C.

The medicated feed should be supplied to the affected pen(s) or group(s) of pigs, chickens, turkeys or ducks. Treatment should be continued for a period of five to seven days for respiratory or systemic infections. During the treatment period, only feed medicated with the product should be supplied.

For incorporation into dry feed at the registered mill. A manufacturer who is approved to incorporate directly at any concentration, veterinary medicinal products or pre-mixtures containing such products must be responsible for mixing when incorporation is less than 2 kg per tonne for final feed.

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: Animals must not be slaughtered for human consumption during treatment.

Pigs	10 days
Chickens	2 days
Turkeys	2 days
Ducks	4 days

Eggs: Chicken's, Turkeys and Ducks - Eggs of treated animals should not be used for human consumption

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, etracyclines

ATCVet Code: QJ01AA03

5.1 Pharmacodynamic properties

Chlortetracycline is a natural broad spectrum antibiotic of the tetracycline group. Its activity is bacteriostatic by interfering with the protein synthesis at the S30 ribosome sub-unit.

At recommended dosages it has no pharmacological effects on cardiovascular, nervous or other body systems.

5.2 Pharmacokinetic particulars

When dosed orally it is quickly absorbed into the blood stream. In-feed dosing provides steady to near steady state plasma levels. This provides effective concentrations in various tissues, including lungs and other respiratory tissues.
The major metabolite is 4-epi-chlortetracycline.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium sulphate dihydrate
Carmellose sodium

6.2 Incompatibilities

None known

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 mashed feed 2 months.
Shelf life after incorporation into pelleted feed 3 weeks.

6.4 Special precautions for storage

Store apart from animal feedingstuffs.
Do not store above 30ºC.
After first opening the bag of premix, any remaining contents should be stored in a dry place and the bag should be closed and secured with a suitable bag tie.

6.5 Nature and composition of immediate packaging

Heat sealed polyethylene bags containing 2 kg, 3 kg, 9 kg, 12 kg, 16 kg, 20 kg and 25 kg.
Cardboard cartons containing 8 x 3 kg polyethylene bags, 12 x 2 kg polyethylene bags

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4007

9. DATE OF FIRST AUTHORISATION

27 May 2005

10. DATE OF REVISION OF THE TEXT

August 2020

Approved 21 August 2020