

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10802/001/001**

Case No: 7007489

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Alpharma BVBA

Laarstraat 16, 2610 Antwerp, Belgium

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Aurofac 100 Granular Premix for Medicated Feeding

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless revoked, shall continue in force from **22/03/2010**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Aurofac 100 Granular Premix for Medicated Feedingstuff

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance

Chlortetracycline Hydrochloride 100 mg

Excipients

Carboxymethylcellulose sodium 20 mg

Calcium sulphate (dihydrate) to 1 g

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Premix for medicated feeding stuff.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs, chickens, turkeys and ducks.

4.2 Indications for use, specifying the target species

As an aid in the treatment and control of respiratory and systemic infections associated with chlortetracycline-sensitive organisms.

4.3 Contraindications

Use in adult ruminants is not recommended.

Do not use in animals known to be hypersensitive to the active substance.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None.

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 sensitised, or if you have been advised not to work with such preparations. Handle the product with great care to avoid exposure, taking all recommended precautions. 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. 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. No studies have been performed in pregnant sows.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

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 hens	20-25 mg/kg bodyweight daily
Turkeys	25-35 mg/kg bodyweight daily
Ducks	25-35 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 Auofac 100 Granular 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 birds.

Treatment should be continued for a period of five to seven days.

During the treatment period, only feed medicated with AUOFAC 100 Granular should be supplied.

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 yeasts and fungi. Under such conditions, withdraw medication and apply appropriate treatment.

4.11 Withdrawal Period(s)

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

Edible tissues:

Pigs:	10 Days
Chickens:	2 Days
Turkeys:	7 Days
Ducks:	7 Days

Eggs:

Chickens 4 days

Eggs from medicated laying hens must not be used for human consumption during treatment.

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.

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carboxymethylcellulose sodium

Calcium sulphate (dihydrate)

6.2 Incompatibilities

None known.

6.3 Shelf-life

Premix: 36 months

Medicated 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.

The container should be closed securely after use

6.5 Nature and composition of immediate packaging

Polyethylene bags containing 3 kg, 4 kg, 9 kg, 12 kg, 16 kg, 25 kg.
Cardboard cartons containing 8 x 3 kg and 5 x 4 kg polyethylene bags.

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

Alpharma Animal Health BVBA
Laarstraat 16
2610 Antwerp
Belgium

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10802/1/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22nd April 2006

10 DATE OF REVISION OF THE TEXT

22nd March 2010