Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

CTC 10 %w/w Premix for Medicated Feed

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains

Active substance
Chlortetracycline hydrochloride 100 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Premix for Medicated Feed

4 CLINICAL PARTICULARS

4.1 Target Species

Calves (less than 6 months of age) and pigs.

4.2 Indications for use, specifying the target species

Calves: The product is indicated as an aid in the treatment of respiratory disease in calves caused by Pasteurella spp., sensitive to chlortetracycline.

Pigs: The product is indicated as an aid in the treatment of respiratory disease in pigs caused by micro-organisms sensitive to chlortetracycline.

4.3 Contraindications

Do not use in adult ruminants, dairy cows and veal calves.
Do not use in animals with known hypersensitivity 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
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. Inappropriate use of the product may increase the prevalence of bacteria resistant to chlortetracycline and may decrease the effectiveness of treatment with related substances, due to the potential for cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
When incorporating into feed, care must be taken not to inhale any dust. It is recommended that a face mask be worn during the dispensing and mixing of the product.
Avoid skin contact when handling this product. Wash hands and all exposed skin at the end of the operation.

4.6 Adverse reactions (frequency and seriousness)

Chlortetracycline toxicity is low. If digestive disturbances do occur, treatment should be discontinued.
Long term use of this product is not recommended as it may lead to the development of bacterial resistance.

4.7 Use during pregnancy, lactation or lay

This product is not recommended for use in pregnant or lactating cows.
This product is safe for use in pregnant sows.

4.8 Interaction with other medicinal products and other forms of interactions

This product is not recommended for concurrent administration with any other oral medication.

4.9 Amounts to be administered and administration route

For oral administration after incorporation in a feedingstuff by a facility licensed to medicate feed.

The recommended therapeutic dose is 20 mg per kg bodyweight daily i.e. 20 grams of *CTC 10% premix* per 100 kg bodyweight.
To achieve this dose, *CTC 10% premix* should be mixed into feed at the following inclusion rates:

Calves:

Calf Bodyweight (kg)	Average Feed Intake Kg feed/day	Inclusion Rate
100 kg	0.8 kg	25 kg per tonne
200 kg	1.6 kg	25 kg per tonne

Pigs:

Age of Pig (weeks-kg)	Average feed intake –kg feed/day	Inclusion rate
8 weeks (20 kg bodyweight)	1 kg	4 kg per tonne
12 weeks (30 kg bodyweight)	1.5 kg	4 kg per tonne
14 weeks (45 kg bodyweight)	2.0 kg	4 kg per tonne
16 weeks (60 kg bodyweight)	2.5 kg	4 kg per tonne

To allow thorough dispersion of the product, CTC 10% premix should first be mixed with 50 kg feed before incorporating into the final feed. Pelleting should not be conducted at temperatures in excess of 70°C.

Treatment should be continued for a period of 7 days.
The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage the chlortetracycline inclusion rate should be adjusted for feed intake.

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

Chlortetracycline toxicity is low. If digestive disturbances do occur, treatment should be discontinued.

4.11 Withdrawal period(s)

Calves: Meat and offal: 35 days
Milk: not applicable. The product is contraindicated for use in adult cattle.

Pigs: Meat and offal: 6 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Tetracycline for systemic use.
ATCvet classification: QJ01A A03

5.1 Pharmacodynamic properties

Chlortetracycline hydrochloride is a bacteriostatic antibiotic, interfering with bacterial protein synthesis of the rapidly growing and reproducing bacterial cell.

5.2 Pharmacokinetic particulars

Following oral absorption, maximum blood levels are achieved in approximately 2-8 hours. The chlorotetracycline plasma concentration maintains a steady state level until day 7, following consecutive twice-daily medication.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal anhydrous silica
Medium chain triglycerides
Soya bean meal

6.2 Major incompatibilities

Incompatible with substances containing ionophores.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life following incorporation into meal or pelleted feed: 1 month

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.

6.5 Nature and composition of immediate packaging

The product is supplied in 25kg LDPE liners.

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

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

7 MARKETING AUTHORISATION HOLDER

Univet Limited
Tullyvin
Cootehill
Co. Cavan.
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10990/039/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 June 2006
Date of last renewal: 21 January 2011

10 DATE OF REVISION OF THE TEXT

February 2020