1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CTC 100 mg/g premix for medicated feeding stuff for calves and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substances:
Chlortetracycline hydrochloride 100 mg

Excipients:

Qualitative composition of excipients and other constituents
Colloidal anhydrous silica
Medium chain triglycerides
Soya bean meal

A yellow uniform meal-like mix

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calves less than 6 months of age) and pigs.

3.2 Indications for use for each target species

Calves:
The veterinary medicinal product is indicated as an aid in the treatment of respiratory disease in calves caused by *Pasteurella spp.,* sensitive to chlortetracycline.
Pigs:
The veterinary medicinal product is indicated as an aid in the treatment of respiratory disease in pigs caused by micro-organisms sensitive to chlortetracycline.

3.3 Contraindications

Do not use in adult ruminants, dairy cows and veal calves.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

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.
Inappropriate use of the veterinary medicinal 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.

Long term use of this veterinary medicinal product is not recommended as it may lead to the development of bacterial 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.
When mixing this veterinary medicinal product, personal protective equipment consisting of protective goggles, impervious gloves and a dust mask to BS 2091 or BS 6061 should be worn, to avoid direct contact with the skin and inhalation of the veterinary medicinal product.
Wash hands and all exposed skin at the end of the operation.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (calves less than 6 months of age) and pigs:

Undetermined frequency (cannot be estimated from the available data):	Gastrointestinal disorder[1]

[1]Treatment should be discontinued.

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 the national competent authority via the national reporting system. See the immediate packaging for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Cattle: This veterinary medicinal product is not recommended for use in pregnant or lactating cows.
Pigs: Can be used in pregnant sows.

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

In-feed use.
Must be incorporated in a feeding stuff by a facility licensed to medicate feed.

The recommended therapeutic dose is 20 mg chlortetracycline per kg bodyweight daily i.e. 20 g of premix per 100 kg bodyweight. To achieve this dose, the veterinary medicinal product 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 veterinary medicinal product, it 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.

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

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

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.

Not applicable.

3.12 Withdrawal periods

Calves:
Meat and offal: 35 days. Not authorised for use in animals producing milk for human consumption.

Pigs:
Meat and offal: 6 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QJO1AA03

4.2 Pharmacodynamics

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

4.3 Pharmacokinetics

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Incompatible with substances containing ionophores.

5.2 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.

5.3 Special precautions for storage

Do not store above 25 °C.
Protect from light.
Keep the container tightly closed after use.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is supplied in 25 kg LDPE liners.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Univet Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10990/039/001

8. DATE OF FIRST AUTHORISATION

23/06/2006

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

17/07/2026

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).