IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10983/002/001**
Case No: 7006260

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:

Vetoquinol Ireland Limited

10 Lad Lane, **Lower Baggot Street**, **Dublin 2**, **Ireland**

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:

Chlortetracycline 0.5g

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 **08/12/2009**.

Signed on behalf of the Irish Medicines Board

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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

Chlortetracycline 0.5 g

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance

Chlortetracycline Hydrochloride	0.500 g

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Intra-uterine tablet.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

Chlortetracycline 0.5 g is indicated for the treatment of retained placenta and metritis, and the prevention and treatment of infectious complications of parturition.

4.3 Contraindications

Do not use the product if uterine tearing is present or suspected.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use

None.

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

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The product is not intended for use in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Intra-uterine administration only.

1 - 2 bolus should be introduced deep into the uterine horns. Repeat after 48 hours if necessary.

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

Chlortetracycline has a high margin of safety. However, there is no specific antidote and in case of overdosage, symptomatic relief should be given.

4.11 Withdrawal Period(s)

Milk: one day (2 milkings in cows milked twice daily).

Meat: 9 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Chlortetracycline is a wide-spectrum antibiotic active against gram-positive and gram-negative aerobic and anaerobic bacteria.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Croscarmellose Sodium
Colloidal Anhydrous Silica
Magnesium Stearate
Talc
Sorbitol

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 12 months.

6.4 Special precautions for storage

Do not store above 25^0C.
Store in a dry place.

6.5 Nature and composition of immediate packaging

A yellow unmarked oblong intrauterine tablet 60×22×11mm, low density polyethylene aluminium foil, 5 tablets per foil in packs of 50 tablets.

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

Vetoquinol Ireland Limited
10 Lad Lane
Lower Baggot Street
Dublin 2
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10983/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT

8th December 2009