

IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10987/049/001**
Case No: 7002142

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) hereby grants to:

Chanelle Pharmaceuticals Manufacturing Limited

Loughrea, Co. Galway, 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:

Chanacin Plus Tablet

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.

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

Chanacin Plus Tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 6 g tablet contains:

Active Substance

Phthalylsulfathiazole 2000 mg

Streptomycin Sulphate 500 mg

Excipients

Ponceau 4R (E124) 4 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

4 CLINICAL PARTICULARS

4.1 Target Species

Calves

4.2 Indications for use, specifying the target species

For the treatment of scour in calves mainly due to *Escherichia coli* and *Salmonella* spp.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

Discontinue treatment after 36-48 hours if no response is observed and review therapy.
Consult your veterinary surgeon if a systemic infection develops.

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

None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration.

Care must be taken to avoid damage to the pharyngeal area if a balling gun is used in administering the product.

Two tablets per 40-60 kg as a first dose and then one tablet twice daily for three days (i.e. 67-100 mg/kg

Phthalylsulfathiazole and 17-25 mg/kg Streptomycin Sulphate initially and half doses subsequently).

It is advisable to withdraw milk from scouring calves and give an electrolyte solution.

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

None.

4.11 Withdrawal Period(s)

Animals intended for human consumption should not be slaughtered during treatment. Animals intended for human consumption should not be slaughtered until 28 days after the last treatment.

Milk: not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Phthalysulphathiazole is a bacteriostatic antibacterial agent which belongs to the sulphonamides. It is given for its antibacterial action in the gastro-intestinal tract, often in combination with other antibacterial agents.

Streptomycin is an aminoglycoside antibiotic which is particularly active against *Mycobacterium tuberculosis* as well as many Gram-negative bacteria.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ponceau 4R (E124)

Maize Starch

Pregelatinised Starch

Talc

Magnesium Stearate

Lactose Monohydrate

6.2 Incompatibilities

None known.

6.3 Shelf-life

The shelf-life expiry date for this product shall not exceed 3 years from the date of its manufacture.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and composition of immediate packaging

Pink bolus shaped tablet.

10's: PVC tray placed in a cardboard carton.

20's: Clear polystyrene pill box.

120's: Polypropylene containers with high density polyethylene lids.

500's: High density polyethylene containers with polypropylene lids.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/49/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

9th May 2004