

IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10987/011/001**
Case No: 7002141

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:

C.N.F Scour Diet Oral Powder

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

CNF Scour Diet Oral Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g sachet contains:

Neomycin sulphate	400.0 mg
Sodium Chloride	5.993 g
Dextrose Monohydrate	84.8 g
Sodium Bicarbonate	3.5 g
Potassium Chloride	3.0 g
Potassium Dihydrogen Phosphate	1.758 g

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral powder

4 CLINICAL PARTICULARS

4.1 Target Species

Calves.

4.2 Indications for use, specifying the target species

For the treatment of diarrhoea in pre-ruminant calves associated with infections caused by organisms known to be, or suspected of being, susceptible to neomycin.

4.3 Contraindications

CNF is contra-indicated in calves hypersensitive to neomycin. Do not administer to calves with known auditory or renal problems.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use

If no improvement is observed within 48 hours of starting treatment, an alternative treatment regime should be considered.

Reconstituted product may be stored in a fridge for up to 48 hours.

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

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.

For two consecutive days, the calf is fed only with CNF Scour Diet. Feed one sachet morning and evening i.e. a full course of treatment consists of four sachets. The contents of one sachet should be mixed with 1/2 litre of cold water. Then add 1/2 to 1 litre of lukewarm water depending on the age of the calf.

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

Not applicable.

4.11 Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment. Animals must not be slaughtered for human consumption until 30 days after last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Neomycin Sulphate is a member of the aminoglycoside group of antibiotics and is bactericidal in action. It penetrates the cell wall and cytoplasmic membrane of susceptible microorganisms, binds to the ribosomes, causes misreading of the genetic code and thus incorrect amino acids are inserted into the peptide chain. Faulty proteins are produced, resulting in the death of the microorganisms. Because it is poorly absorbed, neomycin is effective in the treatment of enteric infections, but not suitable for the treatment of systemic infections. Electrolytes are present to aid in the prevention of dehydration associated with diarrhoea and dextrose as an immediate source of energy.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal Anhydrous Silica

6.2 Incompatibilities

None known.

6.3 Shelf-life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

Protect from light.

Reconstituted product may be stored at 2-8°C (in a fridge) for up to 48 hours.

6.5 Nature and composition of immediate packaging

Foil lined paper sachets containing 100 g.

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

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/11/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2003