IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10987/018/001**
Case No: 7006763

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:

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:

Sulpha No.2 Powder for Oral Solution

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 **02/11/2009**.

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

Sulpha No.2 Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains :
Active substance

Sulfadimidine 99.01% w/w

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Calves

4.2 Indications for use, specifying the target species

Sulpha No. 2 Powder is indicated for use in calves as an anti-bacterial agent effective against sulfonamide sensitive organisms.

4.3 Contraindications

Do not use in animals with serious liver or renal distrubances.
Do not use in animals with known hypersensitivity to sulfonamides.
Do not treat for longer than 7 days.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

Adequate water intake for animals being treated is essential to avoid the occurrence of crystaluria.
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.

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 only, the product should be mixed with milk or water.

To ensure a correct dosage, body weight should be determinated as accurately as possible.

As an initial dose, sulfadimidine 200 mg/kg bodyweight, equivalent to 2g Sulpha No. 2 Powder per 10 kg bodyweight, is recommended.

As a maintenance dose, sulfadimidine 100 mg/kg bodyweight, equivalent to 1 g Sulpha No. 2 Powder per 10 kg bodyweight daily for 5-7 days is recommended.

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

Not applicable.

4.11 Withdrawal Period(s)

Meat and offal: 28 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, sulfadimidine.
ATCvet code: QJ01EQ03

5.1 Pharmacodynamic properties

Sulfadimidine is a member of the sulfonamide group of drugs. The activity of the sulfonamides is bacteriostatic and broad spectrum.
The mechanism of action involves competitive inhibition with PABA in bacterial metabolism thereby blocking functional folic acid synthesis and ultimately leading to decreased purine production, which effectively decreases nucleic acid synthesis. Sulfonamide - sensitive bacteria are unable to utilise a pre-formed source of folic acid. Bacteria which do not require folic acid for growth or can use pre-formed folic acid are resistant to the anti-bacterial actions of sulfonamides. Conversely, animal cells have an absolute requirement for pre-formed folic acid and therefore, sulfonamides do not cause concomitant effects in the host.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal Anhydrous Silica

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 24 hours

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

25 g Foil/paper sachet.
40 g paper/12 g polyethylene/7µ foil/25 g polyethylene.

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 Limited,
Loughrea,
Co. Galway.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/018/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT

2nd November 2009