

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10960/067/001**
Case No: 7006074

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:

Cross Vetpharm Group Ltd.
Broomhill Road, Dublin 24, 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:

Hyspan 400mg 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.

The authorisation,unless revoked, shall continue in force from **20/10/2009**.

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

Hyspan 400mg Oral Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100g sachet contains:

Active Substance

Neomycin Sulphate	400mg
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For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral powder.

White to off-white free-flowing powder.

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*. Specially formulated to combat infection, dehydration and loss of electrolytes.

4.3 Contraindications

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

4.4 Special warnings for each target species

Withdraw all milk and milk replacer from scouring animals.

4.5 Special precautions for use

Special precautions for use in animals

Withdraw all milk and milk replacer from scouring animals.

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 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.

For calves between 35 – 75 kg, 5 sachets are required.

Administer the contents of 1 sachet dispersed in 3 pints of warm water twice daily for 2 days and once on the third day. Start treatment as soon as possible after the start of diarrhoea.

Discontinue treatment after 2 days if no response is observed and consult your veterinary surgeon. Do not extend treatment beyond the recommended time.

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

Not applicable.

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.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Intestinal anti-infectives; Neomycin.

ATCvet Code: QA07AA01.

5.1 Pharmacodynamic properties

Hyspan acts locally on the gastrointestinal tract. Neomycin sulphate is an antibiotic which is poorly absorbed from the gut and is thus present in maximum concentration at the site of infection. The electrolytes restore electrolyte balance and relieve dehydration. Glucose monohydrate is an immediate source of energy which enhances the absorption of electrolytes and water thus speeding rehydration

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Chloride
Potassium Chloride
Sodium Hydrogen Carbonate
Potassium Dihydrogen Phosphate
Silica Colloidal Anhydrous
Glucose Monohydrate

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and composition of immediate packaging

Foil laminated sachet containing 100 g of product.

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

Cross Vetpharm Group Limited
Broomhill Rd
Tallaght
Dublin 24
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10960/067/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT

20th October 2009