IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10999/020/001**
Case No: 7004757

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:

Norbrook Laboratories Limited

Station Works, **Newry**, **Co. Down BT35 6JP**

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:

Norodine 120mg Coated Tablets

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 previously revoked, shall continue in force from **30/09/2008**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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

Norodine 120mg Coated Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:	
Active Substances	
Trimethoprim	20.0 mg
Sulfadiazine	100.0 mg
Excipients	
Titanium Dioxide (E171)	0.625 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Coated tablet.
Off-white, sugar-coated, unscored, circular tablets.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and Adult Cats.

4.2 Indications for use, specifying the target species

In vitro, the product is effective against most common Gram-positive and Gram-negative bacteria including *Escherichia coli, Klebsiella pneumonia, Pasteurella multocida, Streptococcus* spp., *Staphylococcus* spp., *Salmonella* spp., *Corynebacterium* spp., *Proteus mirabilis* and *Citrobacter freundii.*

When susceptible organisms are present, the product is indicated for oral use in dogs for the treatment of alimentary tract infections, respiratory and urogenital infections, skin and wound infections and eye and ear infections.

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 precautions for use in animals

When given to cats, the tablets should not be broken, chipped or halved.
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 epidemiological information about susceptibility of the target bacteria.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the product and may decrease the effectiveness of treatment with other antimicrobials or classes of antimicrobials, due to the potential for cross-resistance.

Special Precautions to be taken by the Person Administering the Medicinal Product to Animals

None.

4.6 Adverse reactions (frequency and seriousness)

A low incidence of polyarthropathy and Keratoconjunctivitis Sicca (Dry Eye) has been reported in dogs following oral administration of potentiated sulfonamides. If either of these conditions occur, it is recommended that medication is stopped and that future treatment is avoided.

4.7 Use during pregnancy, lactation or lay

The product can be safely administered during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No known interactions.

4.9 Amounts to be administered and administration route

To ensure a correct dosage, bodyweight should be determined as accurately as possible.
Administer orally by hand. The daily dose is 30 mg of combined active ingredients per kg bodyweight. This is achieved using the following doses;

Dogs - 1 tablet per 4 kg bodyweight.
Cats - 1 tablet daily

Treatment should be continued until 2 days after clinical signs have resolved up to a maximum of 5 days.

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

Not applicable.

4.11 Withdrawal Period(s)

Not applicable

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Combinations of sulphonamide and trimethoprim, sulfadiazine and trimethoprim.
ATCvet code: QJ01EW10.

5.1 Pharmacodynamic properties

Sulfadiazine (SDZ) inhibits the incorporation of para-aminobenzoic acid into folic acid and trimethoprim (TMP) inhibits the enzyme dihydrofolate reductase (DHFR) which converts dihydrofolic acid into tetrahydrofolic acid. TMP and SDZ act together synergistically with a double-blockade mode of action. The combination is bactericidal inhibiting sequential steps in the synthesis of purines which are required for DNA synthesis. TMP-SDZ combinations have a broad bactericidal action against many gram-positive and gram-negative aerobic bacteria and a large proportion of anaerobic bacteria, chlamydia and protozoa.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose
Lactose
Sodium Starch Glycollate
Povidone
Magnesium Stearate
Purified Water

Coating
Sucrose
Titanium Dioxide (E171)
Talc
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Store below 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

The product is marketed in white polypropylene securitubs sealed with a white polyethylene cap. Each securitub contains 100 Norodine 120mg Coated Tablets.

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

Norbrook Laboratories Limited,
Station Works,
Newry
Co. Down BT35 6JP,
N. Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10999/020/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT