IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10999/014/001**
Case No: 7003347

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, **Camlough Road**, **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:

Betamox 400 mg 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 **30/09/2007**.

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

Betamox 400 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Amoxicillin Trihydrate 0.460 g equivalent to 400.00 mg amoxicillin.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Tablet. White to off-white oblong scored tablet

4 CLINICAL PARTICULARS

4.1 Target Species

Calves

4.2 Indications for use, specifying the target species

Betamox 400 mg Tablets are indicated for the treatment of enteritis, salmonellosis and septicaemia in calves. Betamox 400 mg Tablets may also be effective in the treatment of bacterial pneumonia. Amoxycillin is a broad spectrum semi-synthetic penicillin, bactericidal in action. In *vitro* it is effective against a wide range of Gram-positive and Gram-negative bacteria found in calves which include: *Clostridium* spp, *Corynebacterium pyogenes*, *Pasteurella* spp, *Salmonella* spp, Streptococci and Staphylococci (penicillin sensitive strains). Effect has been observed against *Escherichia coli*.

4.3 Contraindications

Betamox 400 mg Tablets should not be used in animals with functionally mature rumens.
Betamox 400 mg Tablets are contra-indicated in animals known to be hypersensitive to amoxicillin/penicillin.
Not to be administered to lactating cows, or small herbivores.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

2. Handle this product with care to avoid exposure.

3. If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

This product is not intended for use in pregnant or lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The recommended dose rate is 8 mg amoxycillin per kg bodyweight given twice daily for up to five consecutive days. This is achieved as follows:

Calves per 50 kg: 1 tablet twice daily.

Betamox 400 mg Tablets may be administered by hand or by balling gun.

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. Cattle may be slaughtered for human consumption only after 10 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Beta-lactam antibacterials
ATCvet Code: QJ01CA04

5.1 Pharmacodynamic properties

Amoxycillin predominately inhibits cell wall synthesis in susceptible bacteria. Amoxycillin has a unique mode of action which directly and irreversibly disrupts existing cell wall peptidoglycan rather than newly forming peptidoglycan of the divisory septal wall as with other members of the penicillin family.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Lactose
Sodium starch glycollate
Povidone
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25^{o}C.
Store in a dry place.

6.5 Nature and composition of immediate packaging

Betamox 400 mg Tablets are supplied in injection moulded polypropylene tamperproof containers of 20 and 50 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,
Northern Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10999/14/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2002 / 30th September 2007