IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10976/013/001**
Case No: 7001932

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:

Franklin Pharmaceuticals Ltd.

Athboy Road, **Trim**, **Co. Meath**, **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:

Ampisol 2 g

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 **17/12/2006**.

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

Ampisol 2g

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Ampicillin (as Ampicillin Sodium Ph. Eur) 2g/vial

Excipients:

None

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder for solution for injection
A white or off-white powder

4 CLINICAL PARTICULARS

4.1 Target Species

Horses

4.2 Indications for use, specifying the target species

For the treatment and control of respiratory tract, alimentary tract and urogenital tract infections.

4.3 Contraindications

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

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals
Avoid introduction of contamination during use.
Use immediately after reconstitution.

Special precautions to be taken by the person administering the veterinary 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 reaction with cephalosporins and vice versa.
Allergic reaction to these substances may occasionally be serious.
Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
Handle this product with care to avoid exposure.
If you develop symptoms following exposure, such as a 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 may require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Occasional hypersensitivity and anaphylactic reaction may occur.

4.7 Use during pregnancy, lactation or lay

Not recommended.

4.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration with other anti-infectives and antibiotics should be avoided.

4.9 Amounts to be administered and administration route

6 mg to 22 mg per kg bodyweight by intramuscular or intravenous injection.

The higher levels are generally required when treating Gram negative infections and young animals.
Treatment should be repeated at 12 to 24 hour intervals.

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

Not applicable.

4.11 Withdrawal Period(s)

Meat: 6 months.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QJ01CA01
Pharmacotherapeutic Group: Anti-infectives for systemic use, ampicillin

5.1 Pharmacodynamic properties

Ampicillin is a broad spectrum bactericidal antibiotic, active against Gram +ve and Gram -ve organisms.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

None known

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and composition of immediate packaging

10ml type II Vials (Clear) sealed with bromobutyl rubber bungs (grey) and overseals (aluminium)

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 national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Franklin Pharmaceuticals Limited,
Athboy Road,
Trim,
Co Meath.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10976/013/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18th December 2001

10 DATE OF REVISION OF THE TEXT