IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10126/040/001**
Case No: 7004807

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:

Bimeda Chemicals

Broomhill Road, **Tallaght**, **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:

Bilosin 200 mg/ml Solution for Injection

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

Bilosin 200 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active Substance	
Tylosin	200.00 mg
Excipients	
Benzyl Alcohol (preservative)	41.66 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear yellow solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the target species

For the treatment in pigs of diseases involving organisms sensitive to tylosin, such as swine erysipelas (*Erysipelothrix rhusiopathiae*), vibrionic dysentery and pneumonia (*Mycoplasma hyopneumoniae*).

4.3 Contraindications

Do not use in animals known to be hypersensitive to the active ingredient.

4.4 Special warnings for each target species

Not applicable.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Avoid skin contact with the preparation.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Occasionally swelling at the injection site may occur, but this effect is transient.

4.7 Use during pregnancy, lactation or lay

Reports of adverse reproductive effects have not been noted during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

0.5 mls/10 kg bodyweight, equivalent to 10 mg of tylosin per kg bodyweight, by intramuscular injection every 12 hours, up to a maximum of 6 injections. Do not inject more than 5 ml at a single injection site. If a larger injection volume is necessary, it should be divided and administered at different injection sites.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

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

Tolerance studies of up to 156% of the recommended dosage rate have been carried out with localised swelling at the injection site being the only adverse effect.

4.11 Withdrawal Period(s)

Meat and offal: 21 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinfectives for systemic use, macrolides.
ATCvet code: QJ01FA90

Bilosin 200 injection is an antibiotic preparation for parenteral administration to pigs. The active ingredient is Tylosin, each ml of Bilosin 200 containing 200 mg of the active ingredient. Tylosin is a macrolide antibiotic which acts by interfering with bacterial protein synthesis. It has a spectrum of activity and mode of action similar to that of erythromycin. Unlike most antibiotics, its use is restricted to the veterinary field.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Propylene Glycol
Water for Injections

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Multidose 100 ml amber Type II vials sealed with a bromobutyl rubber stopper, and capped with aluminium overseals.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Bimeda Chemicals Ltd.,
Broomhill Road,
Tallaght,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10126/040/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT