[Version 9,03/2022]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bilosin 200 mg/ml Solution for Injection for Pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains
Active substance:
Tylosin 200.00 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl Alcohol	41.66 mg
Propylene Glycol	
Water for Injections	

A clear yellow solution.

3. CLINICAL INFORMATION.

3.1 Target Species

Pigs.

3.2 Indications for use for each 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*).

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

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

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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 correct dosage body weight should be determined as accurately as possible to avoid underdosing **.**

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 16 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01FA90

4.2 Pharmacodynamics

The veterinary medicinal product is an antibiotic preparation for parenteral administration to pigs. The active ingredient is Tylosin, each ml of the veterinary medicinal product 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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

5.3 Special precautions for storage

Do not store above 25°C.

5.4 Nature and composition of immediate packaging

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

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited,

7. MARKETING AUTHORISATION NUMBER(S)

VPA 22033/036/001

8. DATE OF FIRST AUTHORISATION/

Date of first authorisation: 01 October 1988

9. DATE OF THE LAST REVISION OF THE TEXT SUMMARY OF THE PRODUCT CHARACTERISTICS

MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).