# ANNEX III

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**Label Text**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bilosin 200mg/ml Solution for Injection

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: 200 mg of Tylosin Base activity. Also contains Benzyl alcohol 41.66mg/ml as a preservative.

## 3. PHARMACEUTICAL FORM

**Presentation:** A clear yellow, sterile solution suitable for parenteral administration.

## 4. PACKAGE SIZE

100ml

## 5. TARGET SPECIES

**Pigs**
**Uses:** For the treatment in pigs of diseases involving organisms sensitive to tylosin, such as swine erysipelas, and mycoplasma pneumonia. Official, national and regional antimicrobial policies should be taken into account when the product is used.

## 6. INDICATION(S)

**Contra-indications, Warnings, etc.:**
In case of accidental skin or eye contact, wash the affected area with clean water. Seek medical attention if irritation persists.
Care should be taken to avoid accidental self-injection. If accidental self-injection occurs, seek medical advice immediately.
Wash hands after use.
Tylosin and other macrolides may occasionally cause severe allergic reactions.
See package leaflet for full user warnings.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

**Dosage and Administration:** 0.5 ml/10 kg bodyweight, by deep intramuscular injection every 12 hours, up to a maximum of 6 injections. Do not inject more than 5 ml at a single injection site. To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. Do not use in animals hypersensitive to tylosin**.**

## 8. WITHDRAWAL PERIOD

**Withdrawal Periods:** Pigs 16 days.

## 9. SPECIAL WARNING(S), IF NECESSARY

Wash hands after use

## 10. EXPIRY DATE

Expiry Date:

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Protect from light.
**Pharmaceutical Precautions:** Following withdrawal of the first dose use the product within 28 days. Once broached, use by: ___/___/___

## 12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

**Disposal:** Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription. POM- V

## 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children.

## 14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght,
Dublin 24
Ireland

## 16. MARKETING AUTHORISATION NUMBER

Vm 50146/4026

## 17. MANUFACTURER'S BATCH NUMBER

Batch No:

# PACKAGE LEAFLET

Bilosin 200mg/ml Solution for Injection

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland

Manufacturers:
Bimeda MTC Animal Health, 420 Beaverdale Road, Ontario, N3C 2W4, Canada
Eurovet Animal Health BV, Handelsweg 25, 5531 AE BLADEL, Netherlands

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bilosin 200mg/ml, Solution for injection

## 3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

| | |
|---|---|
| Tylosin Base | 200 mg/ml |
| Benzyl Alcohol | 41.66mg/ml |

## 4. INDICATIONS

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

## 5. CONTRAINDICATIONS

Not to be used in animals known to be hypersensitive to the active ingredient.

## 6. ADVERSE REACTIONS

None known. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Pigs.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

0.5 ml /10 kg bodyweight, equivalent to 10 mg of tylosin per kg bodyweight, by deep intramuscular injection every 12 hours, up to a maximum of 6 injections.
Do not inject more than 5 mls at a single injection site.

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid under dosing.

## 9. ADVICE ON CORRECT ADMINISTRATION

None.

## 10. WITHDRAWAL PERIOD

Pigs (meat & offal): 16 days

## 11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Keep out of reach and sight of children.
Following withdrawal of the first dose use the product within 28 days.
Discard unused material.
When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the vial should be discarded should be worked out. This discard date should be written in the space provided.

## 12. SPECIAL WARNINGS

### Special precautions for use in animals

Not recommended for horses.
Official, national and regional antimicrobial policies should be taken into account when the product is used.
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. The lowest recorded $LD_{50}$ for tylosin from other acute toxicity studies was 400mg/kg bodyweight (40 times the recommended dosage rate) by intravenous injection in mice.

### Use during pregnancy and lactation

Reports of adverse reproductive effects have not been noted. Use with care in pregnant animals.

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

Care should be taken to avoid accidental self-injection. If accidental self-injection occurs, seek medical attention immediately. In the event of accidental skin contact, wash thoroughly with soap and water. Wash hands after use. Tylosin may induce irritation. Macrolides, such as tylosin, may also cause hypersensitivity (allergy) following injection, inhalation, ingestion or contact with skin or eye. Hypersensitivity to tylosin may lead to cross reactions to other macrolides and vice versa. Allergic reactions to these

substances may occasionally be serious and therefore direct contact should be avoided. If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips

and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2020

## 15. OTHER INFORMATION

UK authorised veterinary medicinal product.

MA No. Vm 50146/4026

Legal Category: POM-V To be supplied only on veterinary prescription.
Package Quantities:
Multidose vials of 100 ml.

Distributed by:
Bimeda ®
Cross Vetpharm Group UK Ltd.
Unit 2, Bryn Cefni
Llangefni
Anglesey
LL77 7XA,
United Kingdom
FOR ANIMAL TREATMENT ONLY

Approved 18 June 2020