ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

100ml Label and 100ml Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bilovet 200 mg/ml Solution for Injection for cattle and pigs.

Tylosin

2. STATEMENT OF ACTIVE SUBSTANCES

Tylosin 200mg/ml (equivalent to 200,000 IU/ml)
Benzyl alcohol 41.66 mg/ml (preservative)

3. PHARMACEUTICAL FORM

[The pharmaceutical form has to be mentioned on the outer package only.]

Solution for injection.

4. PACKAGE SIZE

100ml

5. TARGET SPECIES

Cattle and pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal Periods:

Pigs:	Meat and offal; 16 days
Cattle:	Meat and offal; 28 days
	Milk; 120 hours.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once broached use by 28 days.

[The following statement and space for the discard date for the broached vial is not required on the immediate label if there are space limitations. It is required on the outer carton.]

Once broached, use by: ___ / ___ / ___

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Protect from light.

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

[Not requested on the immediate label.]

Disposal: read package leaflet.

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.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 50146/4016

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Bilovet 200 mg/ml Solution for Injection for cattle and pigs.

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

Marketing authorisation holder:
Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

Manufacturer responsible for batch release:
Labiana Life Sciences S.A.
Calle Venus 26,
Can Parellada,
Terrassa, 08228,
Spain.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bilovet 200 mg/ml Solution for Injection for cattle and pigs.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Per ml:

Active substance:
Tylosin 200 mg (equivalent to 200,000 IU/ml)

Excipient:
Benzyl alcohol 41.66 mg

The product is a clear, yellow aqueous solution.

4. INDICATION(S)

The product is indicated for use in infections caused by microorganisms susceptible to tylosin.
Cattle (adult):
- Treatment of respiratory infections, metritis caused by Gram-positive micro-organisms, mastitis caused by *Streptococcus* spp., *Staphylococcus* spp. and interdigital necrobacillosis, caused by *Fusobacterium necrophorum* i.e. panaritum or foot rot.

Calves:
- Treatment of respiratory infections and necrobacillosis (calf diphtheria cause by *Fusobacterium necrophorum)*.

Pigs:

- Treatment of enzootic pneumonia caused by *Mycoplasma hyopneumoniae*, haemorrhagic enteritis, (Porcine proliferative haemorrhagic enteropathy due to *Lawsonia intracellularis),* erysipelas caused by *Erysipelothrix rhusiopathiae* and metritis.
- Treatment of arthritis caused by *Mycoplasma* and *Staphylococcus* spp.

5. CONTRAINDICATIONS

The product should not be given to chickens or turkeys.
Do not administer to horses or other equines in which injection of tylosin may be fatal.
Do not administer to animals with known hypersensitivity to tylosin, other macrolides or any of the excipients.

6. ADVERSE REACTIONS

Possible adverse reactions attributed to the product when used as recommended and their frequency are: In very rare cases the following have been observed;

- swelling/inflammation at the site of injection,
- vulval swelling in cattle,
- oedema of the rectal mucosa, partial anal protrusion (‘rosebudding’), erythema and pruritus in pigs.
- Anaphylactic shock and death.

Blemishes may occur at the site of injection and can persist for up to 21 days following administration.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and pigs.

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

For intramuscular injection:

Cattle: 5-10 mg tylosin/kg bodyweight per day for 3 days (2.5 to 5 ml solution for injection per 100 kg bodyweight). Maximum injection volume per injection site should not exceed 15 ml.

Pigs: 5-10 mg tylosin/kg bodyweight per day for 3 days (2.5 to 5 ml solution for injection per 100 kg bodyweight). Maximum injection volume per injection site should not exceed 5 ml.

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

The closure should not be pierced more than 30 times.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD(S)

Pigs: Meat and offal; 16 days

Cattle: Meat and offal; 28 days
Milk; 120 hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C.
Protect from light.
Shelf life after first opening of the immediate packaging: 28 days.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial label.

12. SPECIAL WARNING(S)

Special precautions for use in animals

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information about susceptibility of the target bacteria.

For administration by the intramuscular route only.
Use different injection sites for repeat injections.

Use of the product deviating from the instructions given in this leaflet may increase the prevalence of bacteria resistant to the tylosin and may decrease the effectiveness of treatment with other macrolide antibiotics, due to the potential for cross-resistance.

The efficacy data do not support the use of tylosin for the treatment of bovine mastitis caused by *Mycoplasma* spp.

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

Care should be taken to avoid accidental self-injection.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician

In the event of accidental skin contact, wash thoroughly with soap and water. In case of accidental eye contact, flush the eyes with plenty of clean, running 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.

Do not handle the product if you are allergic to ingredients in the product.

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.

Other precautions

None.

Use during pregnancy, lactation or lay

No adverse effects to tylosin have been seen in fertility, multi-generation or teratology studies.
Use only in accordance with the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction

Lincosamide and aminoglycoside antibiotics can antagonise the action of tylosin.

Overdose

Pigs and calves: Intramuscular injection of 30mg/kg bodyweight per day (three times maximum recommended dose) for five days produced no adverse effects.

Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack size 100ml.

Approved 07 August 2023