1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:

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

Excipient:

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	\
Sodium hydroxide (for pH adjustment)	\
Hydrochloric acid (for pH adjustment)	\
Water for Injection	\

Clear, yellow aqueous solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and pigs.

3.2 Indications for use for each target species

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.

3.3 Contraindications

Do not use in chickens or turkeys.
Do not use in horses or other equines in which injection of tylosin may be fatal.
Do not use in cases of hypersensitivity to the active substance, other macrolides or any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal 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 veterinary medicinal product' deviating from the instructions given in the SPC 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 veterinary medicinal product' if you are allergic to ingredients in the veterinary medicinal 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.
Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling, injection site inflammation Swollen vulva Anaphylactic shock Death
Undetermined frequency (cannot be estimated from the available data):	Injection site reaction[1]

[1] Blemishes, can persist for up to 21 days following administration

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Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling, injection site inflammation Rectal oedema[1], anaphylactic shock, Anal prolapse (partial)[2], Erythema, pruritus, Death
Undetermined frequency (cannot be estimated from the available data):	Injection site reaction [3]

[1] Of the mucosa
[2] 'Rosebudding'.
[3] Blemishes, can persist for up to 21 days following administration.

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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and Lactation:
Use only according to the benefit/risk assessment by the responsible veterinarian.

Fertility:
No adverse effects to tylosin have been seen in fertility, multi-generation or teratology studies.

3.8 Interaction with other medicinal products and other forms of interaction

Lincosamide and aminoglycoside antibiotics can antagonise the action of tylosin.

3.9 Administration routes and dosage

Intramuscular use:

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.

The closure should not be pierced more than 30 times.

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

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

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

Pigs: Meat and offal; 16 days

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01FA90

4.2 Pharmacodynamics

Tylosin is a macrolide antibiotic produced by a strain of *Streptomyces fradiae*. It exerts its antimicrobial effect by binding to the 50S ribosomal subunit and inhibiting protein synthesis in susceptible micro-organisms. Macrolides are generally considered bacteriostatic at therapeutic concentrations and this action is time dependent.
The tylosin spectrum of activity includes Gram-positive bacteria, some Gram-negative strains such as *Pasteurella* and *Mycoplasma* spp at concentrations of 16µg/ml or less. It is not generally active against anaerobes.

4.3 Pharmacokinetics

Absorption: Following intramuscular injection, tylosin blood levels peak 1-2 hours post-injection. Duration of activity is approximately 12 hours.

Distribution, Biotransformation and Elimination: Tylosin levels of 1.4 to 1.6 and 2.2 to 6.7 µg/ml were recorded in serum and lung tissue respectively following intramuscular injection of 8.8mg/kg bodyweight in pigs. Measurable amounts of tylosin were still present in both serum and lung tissue at 12 hours post injection. Tylosin concentrations were greater in lung tissue than serum at all sample times.

Environmental properties

Tylosin is persistent in some soils.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening of the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

100 ml, Type II amber glass vials sealed with a bromobutyl rubber bung with aluminium overseal and packaged in a cardboard carton.

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.
The veterinary medicinal product should not enter water courses as tylosin may be dangerous for fish and other aquatic organisms.

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 Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA22033/055/001

8. DATE OF FIRST AUTHORISATION

09/01/2015

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

06/02/2025

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).