ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylovectin 200 solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Tylosin 200 000 IU

3. PACKAGE SIZE

50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle, goats and pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular or slow intravenous (cattle only) injection

7. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle:
Meat and offal – 28 days
Milk – 108 hours
Goat:
Meat and offal – 42 days
Milk – 108 hours
Pigs:
Meat and offal – 16 days

8. EXPIRY DATE

Exp {mm/yyyy}
Once broached use within 28 days.

9. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Do not freeze.
Keep the vial in the outer carton in order to protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium

14. MARKETING AUTHORISATION NUMBER

Vm 30282/3013

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylovectin 200 solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Tylosin 200 000 IU

3. TARGET SPECIES

Cattle, goats and pigs.

4. ROUTES OF ADMINISTRATION

Intramuscular or slow intravenous (cattle only) injection
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle:
Meat and offal– 28 days
Milk – 108 hours
Goat:
Meat and offal – 42 days
Milk – 108 hours
Pigs:
Meat and offal – 16 days

6. EXPIRY DATE

Exp {mm/yyyy}
Once broached use within 28 days.

7. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Do not freeze.

Keep the vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Tylovectin 200 solution for injection for cattle, goats and pigs

2. Composition

Each ml contains:

Active substance:

Tylosin 200 000 IU

Excipient:

Benzyl alcohol (E1519) 40 mg

A pale yellow to amber-coloured liquid.

3. Target species

Cattle, goats and pigs.

4. Indications for use

For the treatment of specific infections (listed below) caused by microorganisms susceptible to tylosin.

Cattle (ruminants):

Respiratory infections, metritis caused by Gram-positive microorganisms, mastitis caused by *Streptococcus spp*, *Staphylococcus spp* and interdigital necrobacillosis, i.e. panaritium or foot rot.

Cattle (calves):

Respiratory infections and necrobacillosis.

Pigs:

Enzootic pneumonia, haemorrhagic enteritis, erysipelas and metritis.

Arthritis caused by *Mycoplasma spp*. And *Staphylococcus spp.*

Goats:

Respiratory infections, metritis caused by Gram-positive microorganisms, mastitis caused by Gram-positive microorganisms or *Mycoplasma spp..*

5. Contraindications

Do not use in chickens, turkeys and horses.
Do not use in cases of hypersensitivity to the active substance, other macrolides or any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:

Due to likely variability (time, geographical) in susceptibility of bacteria to tylosin, bacteriological sampling and susceptibility testing are recommended. Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.

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

A high rate of *in vitro* resistance has been demonstrated in European strains of *Brachyspira hyodysenteriae* implying that the veterinary medicinal product will not be sufficiently efficacious against swine dysentery.
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.

People with known hypersensitivity to tylosin, benzylalcohol or propylene glycol should avoid contact with the veterinary medicinal product.

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.

Environmental properties
Tylosin is persistent in some soils.

7. 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 available data)	- Hypersensitivity reaction - Injection site lesion (blemishes) [1]

[1] Can persist for up to 21 days following administration

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	- Injection site swelling, injection site inflammation - Anaphylactic shock - Rectal oedema (swelling) - Erythema - Pruritus (itching) - Rectal prolapse (rosebudding - partial) - Death
Undetermined frequency (cannot be estimated from available data)	- Hypersensitivity reaction - Injection site lesion (blemishes) [2]

[2] Can persist for up to 21 days following administration

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

For intramuscular or slow intravenous (cattle only) injection

Cattle: 5000-10 000 IU 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 in cattle.

Goats: 10 000 IU tylosin/kg bodyweight per day for 3 days (5 ml solution for injection per 100 kg bodyweight).

Pigs: 5000 IU to 10 000 IU of tylosin per kg bodyweight per day during 3 days, *i.e* 2.5 to 5 ml of solution per 100 kg bodyweight.
In pigs do not administer more than 5 ml per injection site.

Where repeat injections are to be administered, use different sites for each injection.

To ensure a correct dosage, body weight should be determined as accurately as possible

The closures should not be broached more than 15 times. In order to prevent excessive broaching of the stopper, a suitable multiple dosing device should be used.

9. Advice on correct administration

None.

10. Withdrawal periods

Cattle:
Meat and offal – 28 days
Milk – 108 hours

Goat:
Meat and offal – 42 days
Milk – 108 hours

Pigs:
Meat and offal – 16 days

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C
Do not freeze.
Keep the vial in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days

12. Special precautions for disposal

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 applicable national collection system. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation number and pack sizes

Vm 30282/3013

Pack sizes:
50 ml
100 ml
250 ml

Not all pack sizes may be marketed

15. Date on which the package leaflet was last revised

November 2023

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

Manufacturer responsible for batch release
Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

Local representatives and contact details to report suspected adverse reactions

17. Other information

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 08 December 2023