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 for cattle, goats and pigs.
Tylosin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Tylosin 200 000 IU

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle, goats and pigs.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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

Dispose of waste material in accordance with local requirements.
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

Huvepharma N.V.
Uitbreidingstraat 80
2600 Antwerp
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 30282/4045

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TYLOVECTIN 200 solution for injection for cattle, goats and pigs.
Tylosin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Tylosin 200 000 IU

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle, goats and pigs.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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

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

Huvepharma N.V.
Uitbreidingstraat 80
2600 Antwerp
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 30282/4045

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
TYLOVECTIN 200 solution for injection for cattle, goats 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:
Huvepharma N.V., Uitbreidingstraat 80, 2600 Antwerp, Belgium

Manufacturer responsible for batch release:
Biovet JSC, 39 Petar Rakov Street, 4550 Peshtera, Bulgaria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

TYLOVECTIN 200 solution for injection for cattle, goats and pigs.
Tylosin

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

Each ml contains:

Active substance:
Tylosin 200 000 IU

Excipient:
Benzyl alcohol (E1519) 40 mg

A pale yellow to amber-coloured liquid.

4. INDICATION(S)

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

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

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 administer to chickens, turkeys or horses.
Do not use in cases of hypersensitivity to tylosin, other macrolides or any of the excipients.

6. ADVERSE REACTIONS

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

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.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, 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, goats and pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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.

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

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 PERIOD(S)

Cattle:
Meat – 28 days
Milk – 108 hours

Goat:
Meat – 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.

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 container: 28 days

12. SPECIAL WARNING(S)

Special precautions for use in animals

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 product is used.

Use of the 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 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.

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

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. 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.

Environmental properties
Tylosin is persistent in some soils.

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

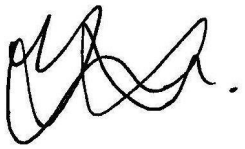
October 2020

15. OTHER INFORMATION

Pack sizes:
50 ml
100 ml
250 ml

Not all pack sizes may be marketed.

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



Approved: 20 October 2020