ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARTON BOX
50/100 /250 ml glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TYLUCYL 200 mg/ml solution for injection for cattle and pigs
tylosin

2. STATEMENT OF ACTIVE SUBSTANCES

tylosin…… 200 000 IU/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml,
100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs

6. INDICATION(S)

Not required

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular or slow intravenous (cattle only) use.

Cattle:
2.5 to 5 ml of solution per 100 kg bodyweight per day during 3 days.

Pigs (more than 25 kg):
2.5 to 5 ml of solution per 100 kg bodyweight per day during 3 days.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle:
Meat and offal: 28 days
Milk: 108 hours

Pigs:
Meat and offal: 16 days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the immediate packaging: 28 days.
Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

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

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

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

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4144

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label of 100 and 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TYLUCYL 200 mg/ml solution for injection for cattle and pigs
Tylosin

2. STATEMENT OF ACTIVE SUBSTANCES

tylosin……200 000 IU/ml

3. PHARMACEUTICAL FORM

Not requested

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs

6. INDICATION(S)

Not included

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular or slow intravenous (cattle only) use.
Cattle:
2.5 to 5 ml of solution per 100 kg bodyweight per day during 3 days.

Pigs (more than 25 kg):
2.5 to 5 ml of solution per 100 kg bodyweight per day during 3 days.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle:
Meat and offal: 28 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}
Shelf-life after first opening the immediate packaging: 28 days.

Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

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

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

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

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4144

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label of 50 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TYLUCYL 200 mg/ml solution for injection for cattle and pigs
Tylosin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

tylosin…… 200 000 IU/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 m

4. ROUTE(S) OF ADMINISTRATION

IM or IV.

Cattle:
2.5 to 5 ml of solution per 100 kg bodyweight per day during 3 days.

Pigs (more than 25 kg):
2.5 to 5 ml of solution per 100 kg bodyweight per day during 3 days.

Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle:
Meat and offal: 28 days
Milk: 108 hours

Pigs:
Meat and offal: 16 days

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the immediate packaging: 28 days
Once broached, use by:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

TYLUCYL 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:
Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

Manufacturer responsible for batch release:
VETOQUINOL SA
MAGNY-VERNOIS
F-70200 LURE
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

TYLUCYL 200 mg/ml solution for injection for cattle and pigs
tylosin

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

Each ml contains:

tylosin…… 200 000 IU
(equivalent to approximately 200 mg)

Excipient(s):
Benzyl alcohol (E1519)..... 40 mg

Solution for injection.
Pale yellow to amber coloured solution.

4. INDICATION(S)

For the treatment of specific infectious conditions (stated 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 root**.**

Calves:
-Respiratory infections and necrobacillosis.

Pigs (more than 25 kg):
-Enzootic pneumonia, haemorrhagic enteritis, erysipelas and metritis.
-Arthritis caused by *Mycoplasma* spp. and *Staphylococcus* spp*.*

For information regarding swine dysentery see section 12.

5. CONTRAINDICATIONS

Do not use in horses.
Intramuscular injection can be fatal in chickens and turkeys.
Do not use in known cases of hypersensitivity to tylosin, other macrolides or to any of the excipients.

6. ADVERSE REACTIONS

Hypersensivity reactions may occur (uncommon).
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 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" and "Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle, pigs

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

Intramuscular or slow intravenous (only in cattle) use.

Cattle:
5 mg to 10 mg of tylosin per kg bodyweight per day during 3 days, i.e 2.5 to 5 ml of solution per 100 kg bodyweight.

Maximum injection volume per injection site should not exceed 15 ml.

Pigs (more than 25 kg):
5 mg to 10 mg 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.

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

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

10. WITHDRAWAL PERIOD(S)

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

Pigs:
Meat and offal: 16 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in the original package.
Keep the vial in the outer carton in order to protect from light.
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 carton and vial label after “EXP”. The expiry date refers to the last day of that month.

Shelf-life after first opening the container: 28 days.

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 carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Use of the product should be based on identification and susceptibility testing of the target pathogens. If it is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target bacteria at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

Use of the product deviating from the instructions given in the package leaflet 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 *Mycoplama* spp. Use of tylosin in this case presents a serious concern to animal and human health, potentially delaying a correct diagnosis, enabling the spread of the pathogen to other cows, impeding efficient/prudent control measures and increasing the risk for the development of antimicrobial resistance.

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.
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.

Use during pregnancy, lactation or lay:
Studies in laboratory animals have neither produced any evidence of a teratogenic or foetotoxic effects nor consequences on animals' fertility.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in the target species. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
In pigs and calves an intramuscular injection of 30 mg/kg per day during 5 consecutive 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.

Environmental properties
Tylosin is persistent in some soils.

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

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2020

15. OTHER INFORMATION

50 ml, 100 ml or 250 ml colourless type II glass vials closed with a bromobutyl rubber stopper and aluminium cap.
One vial per carton.
Not all pack sizes may be marketed.

Approved 18 December 2020