ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

50/100 /250 ml glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Tylosin 200mg/ml

3. PHARMACEUTICAL FORM

Solution for injection.
A pale yellow to amber-coloured liquid.

4. PACKAGE SIZE

50 (100 and 250ml)

5. TARGET SPECIES

Cattle and pigs.

6. INDICATION(S)

Read the package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use
Read the package leaflet before use

8. WITHDRAWAL PERIODS

Pigs: Meat and offal – 16 days
Cattle: Meat and offal– 28 days
Milk: 108 hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once broached use within 28 days. Discard any unused material.
Once opened, use by

11. SPECIAL STORAGE CONDITIONS

Protect from light. Store in the original container. Do not store above 25 °C. Do not freeze.

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

See 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 NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium
Tel: +32 3 288 1849
Fax: + 32 3289 7845
E-mail: customerservice@huvepharma.com

16. MARKETING AUTHORISATION NUMBER(S)

Vm 30282/4028

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

50/100 /250 ml glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Tylosin 200mg/ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 (100 and 250ml)

5. TARGET SPECIES

Cattle and pigs.

6. INDICATION(S)

Read the package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use
Read the package leaflet before use

8. WITHDRAWAL PERIODS

Pigs: Meat and offal – 16 days
Cattle: Meat and offal– 28 days
Milk: 108 hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}

Once broached use within 28 days. Discard any unused material.
Once opened, use by

11. SPECIAL STORAGE CONDITIONS

Protect from light. Store in the original container. Do not store above 25 °C .Do not freeze.

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

See 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 NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium
Tel: +32 3 288 1849
Fax: + 32 3289 7845
E-mail: customerservice@huvepharma.com

16. MARKETING AUTHORISATION NUMBER(S)

Vm 30282/4028

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET
PHARMASIN 200 mg/ml Solution for Injection for cattle and pigs
tylosin

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 NV, Uitbreidingstraat 80, 2600 Antwerpen, Belgium

Manufacturer responsible for batch release

Biovet JSC, 39 Petar Rakov Str, 4550 Peshtera - Bulgaria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PHARMASIN 200 mg/ml solution for injection for cattle and pigs.

tylosin

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

Active substance:
Tylosin 200mg/ml

Excipients:
Benzyl alcohol (E1519) 40 mg/ml.
Propylene glycol
Water for injections

A pale yellow to amber-coloured liquid.

4. INDICATION(S)

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

6. ADVERSE REACTIONS

In very rare cases, the following adverse reactions have been observed in animals administered tylosin at the recommended rate:

- Injection site reaction
- 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.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.
The frequency of possible adverse effects is defined using the following convention:
- very common (affects more than 1 animal in 10)
- common (affects 1 to 10 animals in 100)
- uncommon (affects 1 to 10 animals in 1,000)
- rare (affects 1 to 10 animals in 10,000)
- very rare (affects less than 1 animals in 10,000)
- not known (frequency cannot be estimated from the available data)

7. TARGET SPECIES

Cattle and pigs.

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

Amount(s) to be administered and administration route

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). In pigs do not administer more than 5 ml per injection site.

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid under dosing.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIODS

Pigs: Meat and offal– 16 days
Cattle: Meat and offal– 28 days.
Milk: 108 hours.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Shelf life after first opening the immediate packaging: 28 days. Discard any unused material.

Protect from light. Store in the original container. Do not store above 25°C. Do not freeze.
Do not use after the expiry date stated on the label. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special warnings for each target species

None.

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 (regional, farm level) epidemiological information about susceptibility of the target bacteria.
The efficacy data do not support the use of tylosin for the treatment of bovine mastitis caused by *Mycoplasma* spp.

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

Special precautions for the person administering the veterinary medicinal product to animals

Macrolides, such as tylosin may 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. People with known hypersensitivity to tylosin should avoid contact with 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. Care should be taken to avoid accidental self-injection. If accidental self-injection occurs, seek medical attention immediately.
Tylosin may induce irritation. Avoid skin and/or eye contact. 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.

Use during pregnancy, lactation or lay

Studies in laboratory animals have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. No studies have been conducted 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

Lincosamide and aminoglycoside antibiotics can antagonise the action of tylosin.

Overdose (symptoms, emergency procedures, antidotes), if necessary

Pigs and calves: Intramuscular injection of 30 mg/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

September 2021

15. OTHER INFORMATION

The product is presented in 50,100 or 250 ml Type II colourless glass vials, sealed with a bromobutyl stopper and aluminium cap supplied in a carton. One vial per carton.

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: 02/11/21