

## **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 AND OTHER SUBSTANCES**

Each ml contains:

#### **Active substance:**

Tylosin 200 000 IU

#### **Excipients:**

Benzyl alcohol (E1519) 40 mg

### **3. PACKAGE SIZE**

50 ml

100 ml

250 ml

### **4. TARGET SPECIES**

Cattle, goats and pigs.

### **5. INDICATIONS**

### **6. ROUTES OF ADMINISTRATION**

Read the package leaflet before use.

### **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}

### **9. SPECIAL STORAGE PRECAUTIONS**

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 30282/5011

**15. BATCH NUMBER**

Lot {number}

**16. SPECIAL WARNING(S), IF NECESSARY**

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

Disposal: read the package insert.

**18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

POM-V Veterinary medicinal product subject to prescription

## **PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {BOTTLE}**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Tylovectin 200 solution for injection

### **2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each ml contains:

**Active substance:**

Tylosin                      200 000 IU

### **3. TARGET SPECIES**

Cattle, goats and pigs.

### **4. ROUTES OF ADMINISTRATION**

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}

### **7. SPECIAL STORAGE PRECAUTIONS**

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}

**10. SPECIAL WARNING(S), IF NECESSARY**

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

Disposal: read package leaflet.

**12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE**

For animal treatment only.

## **PARTICULARS TO APPEAR ON THE 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 administer to chickens, turkeys or 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 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 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.

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

### Special precautions for 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 report(s)):	<ul style="list-style-type: none"><li>- Injection site swelling, injection site inflammation</li><li>- Swollen vulva</li><li>- Anaphylactic shock</li><li>- Death</li></ul>
Undetermined frequency (cannot be estimated from available data)	<ul style="list-style-type: none"><li>- Hypersensitivity reaction</li><li>- Injection site lesion (blemishes) <sup>1</sup></li></ul>

Can persist for up to 21 days following administration

Pigs:

Very rare (<1 animal / 10.000 animals treated, including isolated report(s)):	<ul style="list-style-type: none"><li>- Injection site swelling, injection site inflammation</li><li>- Anaphylactic shock</li><li>- Rectal oedema (swelling)</li><li>- Erythema</li><li>- Pruritus (itching)</li><li>- Rectal prolapse (rosebudding - partial)</li><li>- Death</li></ul>
Undetermined frequency (cannot be estimated from available data)	<ul style="list-style-type: none"><li>- Hypersensitivity reaction</li><li>- Injection site lesion (blemishes) <sup>2</sup></li></ul>

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, 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.

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

## **9. ADVICE ON CORRECT ADMINISTRATION**

None.

## **10. WITHDRAWAL PERIODS**

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.

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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

## 13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

## 14. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 30282/5011

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

Not all pack sizes may be marketed

## 15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

November 2023

Find more product information by searching for the 'Product Information Database' or 'PID' on [www.gov.uk](http://www.gov.uk).

## 16. CONTACT DETAILS

Marketing authorisation holder <and contact details to report suspected adverse reactions>

Huvepharma NV  
Uitbreidingstraat 80  
2600 Antwerpen  
Belgium  
+32 3 288 18 49  
[pharmacovigilance@huvepharma.com](mailto:pharmacovigilance@huvepharma.com)

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.

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the right.

Approved 08 December 2023