

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton of 50/100 /250 ml glass vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pharmasin 200 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Tylosin 200 mg

3. PACKAGE SIZE

50 (100 and 250ml)

4. TARGET SPECIES

Cattle, pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Pigs: Meat and offal – 16 days

Cattle: Meat and offal– 28 days

Milk: 108 hours

8. EXPIRY DATE

Exp {mm/yyyy}

Once broached use within 28 days. Discard any unused material.

Once opened, use by

9. SPECIAL STORAGE PRECAUTIONS

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

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 N.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 30282/4028

15. BATCH NUMBER

Lot {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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Tylosin 200 mg

3. TARGET SPECIES

Cattle, pigs.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Pigs: Meat and offal – 16 days

Cattle: Meat and offal– 28 days

Milk: 108 hours

6. EXPIRY DATE

Exp {mm/yyyy}

Once broached use within 28 days. Discard any unused material.

Once opened, use by

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma N.V.

9. BATCH NUMBER

Lot {number}

- Treatment of arthritis caused by *Mycoplasma* and *Staphylococcus* spp.

5. Contraindications

Do not use in chickens or turkeys in which intramuscular injection may be fatal.
Do not use in horses or other equines in which injection of tylosin may be fatal.
Do not use in cases of hypersensitivity to the active substance, other macrolides or to any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:

Use of the veterinary medicinal 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 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.

For administration by the intramuscular route only.

Use different injection sites for repeated injections.

Special precautions to be taken by 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. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

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:

Pigs and cattle (calves): Intramuscular injection of 30 mg/kg bodyweight per day (three times maximum recommended dose) for five days produced no adverse effects.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction
	Swollen vulva
	Anaphylactic shock
	Death
Undetermined frequency (cannot be estimated from the available data):	Blemishes at the injection site 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 reaction
	Rectal oedema
	Anaphylactic shock
	Erythema
	Pruritus (itching)
Undetermined frequency (cannot be estimated from the available data):	Rectal prolapse (partial) ¹
	Death
	Blemishes at the injection site ²

¹ 'Rosebudding'

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 using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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

Intramuscular use:

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

9. Advice on correct administration

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.

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 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 systems. These measures should help to protect the environment.

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 30282/4028

The veterinary medicinal 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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium
+32 3 288 18 49
pharmacovigilance@huvepharma.com

Manufacturer responsible for batch release:

Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

17. Other information

POM-V

Gavin Hall
Approved: 09 September 2025