

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pharmasin 200 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Tylosin 200 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzyl alcohol (E1519)	40 mg/ml
Propylene glycol	
Water for injections	

A pale yellow to amber-coloured liquid.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs.

3.2 Indications for use for each target species

Infections caused by microorganisms susceptible to tylosin.

Cattle (adult):

- Treatment of respiratory infections, metritis caused by Gram-positive microorganisms, mastitis caused by *Streptococcus* spp., *Staphylococcus* spp. and interdigital necrobacillosis caused by *Fusobacterium necrophorum* i.e. panaritium or foot rot

Cattle (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.

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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

¹can 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
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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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 in accordance with the benefit/risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Lincosamide and aminoglycoside antibiotics can antagonise the action of tylosin.

3.9 Administration routes and dosage

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.

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.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Pigs: Meat and offal – 16 days

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01FA90

4.2 Pharmacodynamics

Tylosin is a macrolide antibiotic and exerts its antibiotic activity by a similar mechanism to other macrolides i.e. binding to the 50S fraction of the ribosomes resulting in an inhibition of the synthesis of proteins. Tylosin has mainly a bacteriostatic activity.

Tylosin has an antibiotic effect against Gram positive cocci (Staphylococci, Streptococci), Gram positive bacilli (*Erysipelothrix* spp.), some Gram-negative bacilli (*Pasteurella* spp., *Mannheimia* spp.) and *Mycoplasma* spp.

Resistance to macrolides is usually plasmid-mediated but modification of ribosomes may occur through chromosomal mutation. Resistance can occur by i) decreased entry into bacteria (most common with the gram-negative bacteria), ii) synthesis of bacterial enzymes that hydrolyse the drug and, iii) modification of the target (the ribosome).

This latter resistance type may also lead to cross-resistance with other antibiotics that preferentially bind to bacterial ribosome. Gram-negative anaerobic bacteria are often resistant.

Resistance of *Brachyspira hyodysenteriae* to tylosin has been reported.

4.3 Pharmacokinetics

Absorption: Following intramuscular injection, tylosin blood levels peak 1-2 hours post-injection. Duration of activity is approximately 12 hours.

Distribution, Biotransformation and Elimination: Tylosin levels of 1.4 to 1.6 and 2.2 to 6.7 µg/ml were recorded in serum and lung tissue respectively following intramuscular injection of 8.8 mg/kg bodyweight in pigs. Measurable amounts of tylosin were still present in both serum and lung tissue at 12 hours post-injection. Tylosin concentrations were greater in lung tissue than serum at all sample times.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening of the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is presented in 50ml, 100 ml 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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma N.V.

7. MARKETING AUTHORISATION NUMBER

Vm 30282/4028

8. DATE OF FIRST AUTHORISATION

16 November 2016

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

July 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 09 September 2025