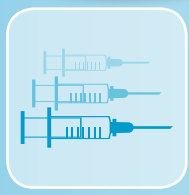
Pharmasin® 200 mg/ml

Solution for injection for
cattle, sheep, goats and pigs



- Contains **tylosin base** – high tissue penetration
- For intramuscular AND (slow) intravenous administration cattle
- **Single** injection results in sufficient tissue concentrations for 24 hours

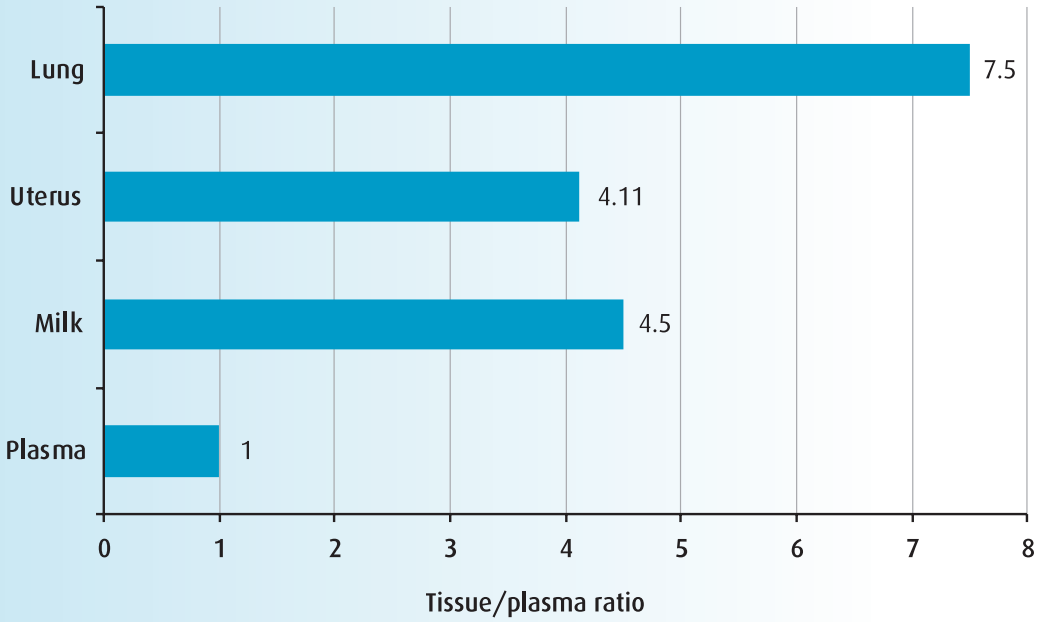


Figure. Tissue/ plasma concentration ratio of tylosin base

Dose Rates

Cattle	:	5-10 mg tylosin/kg BW once per day for 3 days (intramuscular or intravenous).
Sheep and goats	:	10 mg tylosin/kg BW per day for 3 days (intramuscular).
Pigs	:	5-10 mg tylosin/kg BW per day for 3 days (intramuscular).

Withdrawal time:	**Cattle** :	Meat and offal: 28 days. Milk: 108 hours.
	Sheep and goats:	Meat and offal: 42 days. Milk: 108 hours.
	Pigs:	Meat and offal: 14 days.

HUVEPHARMA®
We add performance to your business

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COMPOSITION:
Active substance: Tylosin 200 000 IU/ml
Excipients: Benzyl alcohol (E1519) 40 mg/ml.

INDICATIONS FOR USE:
Infections caused by microorganisms susceptible to tylosin.

Cattle (adult):
Treatment of mastitis caused by *Streptococcus spp., Staphylococcus spp.* or *Mycoplasma*, interdigital necrobacillosis i.e. panaritum or foot rot, respiratory infections, metritis caused by Gram+ microorganisms.

Calves:
Treatment of respiratory infections and necrobacillosis.

Sheep and goats:
Treatment of respiratory infections, metritis caused by Gram+ microorganisms, mastitis caused by Gram+ microorganisms or *Mycoplasma spp.*, interdigital necrobacillosis.

Pigs:
Treatment of enzootic pneumonia, haemorrhagic enteritis, erysipelas and metritis.
Treatment of arthritis caused by *Mycoplasma* and *Staphylococcus spp.*

AMOUNT(S) TO BE ADMINISTERED AND ADMINISTRATION ROUTE:
Intramuscular or slow intravenous injection (only in cattle).

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.

Sheep and goats:
10 mg tylosin/kg bodyweight per day for 3 days (5 ml solution for injection per 100 kg bodyweight).

Pigs:
5-10 mg tylosin/kg bodyweight per day for 3 days (2.5 to 5 ml solution for injection per 100 kg bodyweight).

CONTRAINDICATIONS:
Do not administer to horses. Intramuscular injection can be fatal in chickens and turkeys.
Do not administer to animals with a known hypersensitivity to tylosin or other macrolides.

SPECIAL WARNINGS (FOR EACH TARGET SPECIES):
None.

SPECIAL PRECAUTIONS FOR USE:
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.
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.
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.
If accidental self-injection occurs, seek medical attention immediately.
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.

ADVERSE REACTIONS (FREQUENCY AND SERIOUSNESS):
Blemishes may occur at the site of injection and can persist for up to 21 days following administration.

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:
None known. In the absence of compatibility studies this veterinary product must not be mixed with other veterinary medicinal products.

WITHDRAWAL PERIOD(S):
Cattle: Meat and offal: 28 days.
Milk: 108 hours.
Sheep and goats: Meat and offal: 42 days.
Milk: 108 hours.
Pigs: Meat and offal: 14 days.

NATURE AND COMPOSITION OF IMMEDIATE PACKAGING:
The product is presented in 50 ml, 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.
Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening of the immediate packaging: 28 days. Discard any product remaining in the container at this time.
Protect from light. Store in the original container. Do not store above 25°C. Do not freeze. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

MARKETING AUTHORISATION HOLDER
Huvepharma NV, Uitbreidingstraat 80
2600 Antwerpen, Belgium

For further information, consult your veterinarian surgeon and local country SPC.
Use medicines responsibly - Legal Category: IE POM: UK POM-V.

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