SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pharmasin 100 % w/w Granules for Use in Drinking Water
for Pigs, Chickens, Turkeys and Calves.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1.1 g of granules contains
Active substance:

1000 mg of tylosin (equivalent to 1100 mg of tylosin tartrate)

White to light yellow coloured granules.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calves), pigs, chickens, turkeys.

3.2 Indications for use for each target species

Cattle (calves): Treatment and prevention of pneumonia caused by *Mycoplasma* spp when the disease has been established in the herd.

Pigs: Treatment and prevention of enzootic pneumonia caused by *Mycoplasma hyopneumoniae* and *Mycoplasma hyorhinis* when the disease has been established in the herd.

Treatment and prevention of Porcine Intestinal Adenomatosis (Ileitis) associated with *Lawsonia intracellularis* when the disease has been established in the herd.

Chickens: Treatment and prevention of chronic respiratory diseases (CRD) caused by *Mycoplasma gallisepticum* and *Mycoplasma synoviae* when the disease has been established in the flock.

Treatment and prevention of necrotic enteritis caused by *Clostridium perfringens* when the disease has been established in the flock

Turkeys: Treatment and prevention of infectious sinusitis caused by *Mycoplasma gallisepticum.* When the disease has been established in the flock.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to other macrolides.

Do not use in cases of known resistance to tylosin or cross-resistance to other macrolides (MLS-resistance).

Do not use in animals vaccinated with tylosin-sensitive vaccines either at the same time or within 1 week previously.
Do not use in animals with hepatic disorders.

Do not use in horses because of danger for inflammation of the caecum.

3.4 Special warnings

Due to likely variability (time, geographical) in susceptibility of bacteria to tylosin, bacteriological sampling and susceptibility testing are recommended.

Under-dosing and/or treating for an insufficient length of time are considered to promote the development of resistance in bacteria and should be avoided.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Animals with acute infections may have a reduced water and feed consumption and should be treated with a suitable injectable veterinary medicinal product first.
Do not leave or dispose of water containing tylosin tartrate where it may be accessible to either animals not under treatment or wildlife.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

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.
To avoid exposure during preparation of the medicated drinking water, wear overalls, safety glasses, impervious gloves and wear either a disposable half mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143.

Wash hands after use.

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.

Do not handle the veterinary medicinal product if you are allergic to ingredients in 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.

3.6 Adverse events

Pigs:

Undetermined frequency (cannot be estimated from the available data)	Diarrhoea*, pruritus*, reddening of the skin*, swollen vulva*, rectal oedema* and rectal prolapse*

* all transient and appear 48-72 hours after start of the treatment

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 its local representative or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Laboratory studies in mice and rats 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.

3.8 Interaction with other medicinal products and other forms of interaction

Lincosamides and aminoglycoside antibiotics antagonise the activity of tylosin.

3.9 Administration routes and dosage

Oral administration through the drinking water.
In cattle (calves) the veterinary medicinal product can also be administered through milk or milk replacer.

1.1 gram of the veterinary medicinal product corresponds to 1 gram of tylosin. The dosages are as follows:

Cattle (calves):
10 – 20 mg tylosin per kg BW (corresponding to 11 – 22 mg of the veterinary medicinal product per kg BW), twice daily (corresponding to a daily dose of 20 – 40 mg tylosin per kg BW), for 7 – 14 days.

Turkeys:
75 – 100 mg tylosin per kg BW per day (corresponding to 82.5 – 110 mg of the veterinary medicinal product per kg BW) for 3 – 5 days.

Chickens:
For the treatment of chronic respiratory disease:
75 – 100 mg tylosin per kg BW per day (corresponding to 82.5 – 110 mg of the veterinary medicinal product per kg BW) for 3 – 5 days.

For the treatment of necrotic enteritis:
20 mg tylosin per kg BW per day (corresponding to 22 mg of the veterinary medicinal product) for 3 days.

Pigs:
For the treatment of enzootic pneumonia:
20 mg tylosin per kg BW per day (corresponding to 22 mg of the veterinary medicinal product per kg BW) for 10 days.
For the treatment of ileitis or PIA:
5 – 10 mg tylosin per kg BW per day (corresponding to 5.5 – 11 mg of the veterinary medicinal product per kg BW) for 7 days.

To ensure a correct dosage, body weight should be determined as accurately as possible. The intake of medicated water/milk/milk replacer depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of tylosin may need to be adjusted accordingly. Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{…… mg veterinary medicinal product per kg body weight per day} \times \text{Average bodyweight (kg) of the animals to be treated}}{\text{Average amount of drinking water or milk / animal (l)}} = \text{……mg veterinary medicinal product / l of drinking water}$$

Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. No other source of drinking water should be available during the medication period.

Should there be no clear response to treatment within 3 days the treatment approach should be reconsidered. After the end of the medication period the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance which might support development of resistance.
Medicated water, milk or milk replacer should be replaced every 24 hours.
If individual animals show signs of a serious infection such as a reduced water or feed intake, then they should be treated individually, such as by injection.

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

There is no evidence of tylosin toxicity in rats, at dose rates of up to 1000 mg/kg by the oral route.

There is no evidence of tylosin toxicity in chickens, turkeys, pigs or calves when administered orally at up to three times the recommended dose.

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

Cattle (calves) (meat and offal): 12 days
Pigs (meat and offal): 1 day
Turkeys (meat and offal): 2 days
Turkey (eggs): Zero days
Chickens (meat and offal): 1 day
Chicken (eggs): Zero days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01FA90

4.2 Pharmacodynamics

Tylosin is a macrolide antibiotic produced by a strain of *Streptomyces fradiae.* It exerts its antimicrobial effect by inhibiting protein synthesis of susceptible micro-organisms.
The tylosin spectrum of activity includes amongst others Gram-positive bacteria, some Gram – negative strains such as *Pasteurella*, and *Mycoplasma* spp.

4.3 Pharmacokinetics

In most species peak plasma concentrations have been attained 1 to 2 hours after administration of tylosin. Compared to plasma levels clearly higher tissue concentrations have been observed. Tylosin was extensively metabolised.

Environmental properties
Most of the residues are excreted in faeces predominantly consisting of tylosin (factor A), relomycin (factor D) and dihydrodesmycosin.

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: 3 years

Shelf-life after dilution or reconstitution according to directions:
medicated water:24 hours
medicated milk or milk replacer: 24 hours

Shelf-life after first opening the immediate packaging: 3 months

5.3. Special precautions for storage

Store in the original container in order to protect from light. Store below 30°C.
Keep the container tightly closed.

5.4 Nature and composition of immediate packaging

1.1 kg resealable block bottom zipped sachet made of polyethylene /aluminium/polyethylene terephthalate laminate.

110 g high density polyethylene pot with polypropylene cap.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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 30282/3009

8. DATE OF FIRST AUTHORISATION

06 April 2011

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

September 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).
For UK(NI) only: Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Approved 21 September 2023