SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pharmasin 250 000 IU/g Premix for medicated feeding stuff for pigs, broilers and pullets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Tylosin (as tylosin phosphate) : 250 000 IU

Excipients:

Qualitative composition of excipients and other constituents
Wheat meal
Dipotassium phosphate (E340)
Pregelatinised starch (potato)

Light tan coloured, free flowing granules.

3. CLINICAL INFORMATION

3.1 Target species

Pigs, chickens (broilers and pullets).

3.2 Indications for use for each target species

Pigs

- Treatment and metaphylaxis of Porcine Intestinal Adenomatosis (Ileitis)associated with Lawsonia intracellularis when the disease has been diagnosed at the group or herd level.

Chickens (broilers and pullets:

- Treatment and metaphylaxis of respiratory infections caused by Mycoplasma gallisepticum and Mycoplasma synoviae, when the disease has been diagnosed in the flock.
- Treatment and metaphylaxis of necrotic enteritis caused by Clostridium perfringens, when the disease has been diagnosed in the flock.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, to other macrolides or to any of the excipients.
Do not use where cross-resistance to other macrolides (MLS-resistance)is suspected.
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. Danger of inflammation of the cecum.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Animals with acute infections may have a reduced feed intake and should be treated with a suitable injectable veterinary medicinal product first.

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

Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to tylosin and other macrolides.

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

Tylosin may induce irritation. Macrolides, such a 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.
Personal protective equipment, consisting of overalls, safety glasses, impervious gloves, and 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 should be worn during preparation of the medicated feed. 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.

Special precautions for the protection of the environment

Not applicable.

3.6 Adverse events

Pigs:

Undetermined frequency (cannot be estimated from available data)	- Diarrhoea, rectal prolapse - Rectal oedema - Pruritus, erythema

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
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 population. 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 antagonize the activity of tylosin.

3.9 Administration routes and dosage

Oral use.

Administration through the feed: for the preparation of a medicated feed containing 40 000 000-1 100 000 000 IU tylosin per ton of feed, the required amount of veterinary medicinal product should be homogenously mixed with a suitable carrier into a feed premixture so that at least 5 kg of this premixture can be added to the feed in order to obtain a medicated feed with the required concentration.

For the preparation of medicated feed:
As 1 kg of veterinary medicinal product contains 250 000 000 IU tylosin it follows that 4 mg Pharmasin 250 000 IU/g premix corresponds to 1000 IU tylosin.

The dosages are as follows:

Pigs

For the treatment and metaphylaxis of porcine intestinal adenomatosis (PIA):
4000 – 5000 IU tylosin per kg BW (corresponding to 16 - 20 mg veterinary medicinal product per kg BW) for 3 weeks.

Chickens (broilers and pullets)

For the treatment and metaphylaxis of respiratory infections:
127 000 IU tylosin per kg BW (corresponding to 508 mg veterinary medicinal product per kg BW) for the first 5 days of life

For the treatment and metaphylaxis of necrotic enteritis:
10 000 – 20 000 IU tylosin per kg BW (corresponding to 40 – 80 mg veterinary medicinal product per kg BW) for 7 days.

For the preparation of the medicated feed the body weight of the animals to be treated and their actual daily feed consumption should be taken into due account. Consumption may vary depending on factors like age, breed, husbandry system. To ensure a correct dosage, body weight should be determined as accurately as possible.

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:

$$\frac{\text{…. mg veterinary medicinal product/kg BW/day} \times \text{average body weight (kg) of the animals to be treated}}{\text{Average daily mixed feed intake /kg per animal}} = \text{… mg veterinary medicinal product per kg/ mixed feed}$$

The mixing should be performed by an (authorised) feeding stuff manufacturer with adequate mixing apparatus.

The intake of medicated feed 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.

Should there be no clear response to treatment within 3 days the treatment approach should be reconsidered.

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

Tylosin has been shown to produce no adverse effects when fed to pigs at 600 ppm in the feed (three to six times the recommended dose level) for 28 days. At high levels diarrhoea, apathy, convulsions may occur. The therapy is symptomatic.

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

This veterinary medicinal product is intended to be used for the preparation of medicated feed.

Consideration should be given to official guidance on the incorporation of medicated premixes in final feed.

3.12 Withdrawal periods

Meat & offal.
Pigs: Zero days.
Chickens (broilers and pullets): 1 day.
Not for use in birds producing eggs for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC Vet 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 Gram-positive bacteria, some Gram – negative strains such as Pasteurella, and Mycoplasma spp. at concentrations of 16µg/ml or less.

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 metabolized. Most of the residues are excreted in faeces predominantly consisting of tylosin A, tylosin 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: 2 years.
Shelf life after incorporation into meal or pelleted feed: 3 months.

5.3 Special precautions for storage

Store in a dry place below 30°C. Do not refrigerate or freeze. Protect from frost.
Store in the original container in order to protect from light.

5.4 Nature and composition of immediate packaging

Low-density polyethylene / paper-paper-paper bag with sutured crimp.
Polyethylene/aluminium foil/polyethylene terephthalate sachet.

Pack sizes:
Sachet of 1 kg
Bag of 5 kg
Bag of 20 kg

Not all packs 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 system applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium

7. MARKETING AUTHORISATION NUMBER

Vm 30282/3011

8. DATE OF FIRST AUTHORISATION

20 October 2009

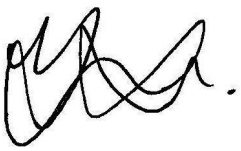
9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

October 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://medicine.health.europa.eu/veterinary).



Approved: 20 February 2024