SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pharmasin 20 000 IU/g Oral Granules for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Tylosin (as tylosin phosphate) : 20 000 IU

Excipients:
Dipotassium phosphate (E340)

For the full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Granules.
Light tan coloured, free flowing granules.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

Pigs: Treatment and metaphylaxis of clinical signs of porcine proliferative enteritis (porcine intestinal adenomatosis, proliferative hemorrhagic enteropathy, ileitis) associated with *Lawsonia intracellularis* when the disease has been diagnosed at the group level.

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

This product is only for administration in small quantities of feed for immediate consumption, to individual animals. 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 take 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.
To avoid exposure during mixing and handling of the veterinary medicinal product wear 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.

Special precautions for the protection of the environment

Not applicable.

Other precautions:

Not applicable

4.6 Adverse reactions (frequency and seriousness)

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 package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
No adverse effects to tylosin have been seen in fertility, multi-generation teratology studies. Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Lincosamides and aminoglycoside antibiotics antagonize the activity of tylosin.

4.9 Amount(s) to be administered and administration route

Oral use.

For use in individual pigs on farms where only a small number of pigs are to receive the medicine. Larger groups should be treated with medicated feeding stuff containing the premix.
Individual pigs should receive 5000 IU tylosin per kg bodyweight, corresponding to 250 mg product/kg bodyweight, once a day for 3 weeks. This is achieved by thoroughly mixing the product into the daily ration for each individual pig. The required amount of product should be added to the estimated quantity of daily ration for each pig in a bucket or similar receptacle and thoroughly mixed. The product should only be added to dry non-pelleted feed.

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

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The veterinary medicinal product 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.

4.11 Withdrawal periods

Pigs

Meat and offal: 1 day.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibacterials for systemic use, macrolides

ATC Vet Code: QJ01FA90

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

Absorption: tylosin reaches maximal blood levels between 1 and 3 hours after an oral dose.
Distribution: after oral doses were given to pigs, tylosin was found in all tissues between 30 minutes and 2 hours after administration, except for the brain and spinal cord. Compared to plasma levels clearly higher tissue concentrations have been observed.
Metabolism and excretion: most of the material excreted through the faeces consists of tylosin (factor A), relomycine (factor D) and dihydrodesmycosin.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Wheat meal
Dipotassium phosphate (E340)
Pregelatinised starch (potato)

6.2 Major Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 3 months.

6.4 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.

6.5 Nature and composition of immediate packaging

Low-density polyethylene / paper-paper-paper bag with sutured crimp.
Pack sizes:
Bag of 1 kg
Bag of 5 kg

Not all pack sizes may be marketed.

6.6 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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 30282/5010

9. DATE OF FIRST AUTHORISATION

04 November 2009

10. DATE OF REVISION OF THE TEXT

October 2023

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V Veterinary medicinal product subject to prescription.

Approved 21 February 2024