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 g contains:

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

Excipients:
For the full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Premix for medicated feeding stuff.Light tan coloured, free flowing granules.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs, broilers and pullets.

4.2 Indications for use, specifying the 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,

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.

4.3 Contraindications

Do not use in animals with known sensitivity to the active substance and/or to any of the excipients of the veterinary medicinal product.
Do not use in animals with known hyper sensitivity to tylosin and other macrolides.
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
Animals with acute infections may have a reduced feed intake and should be treated with a suitable injectable 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 for 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 preparation of the medicated feed, 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 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.

4.6 Adverse reactions (frequency and seriousness)

In pigs, adverse reactions have been observed, including diarrhoea, pruritus, erythema, rectal oedema and prolapse.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interactions

Lincosamides and aminoglycoside antibiotics antagonize the activity of tylosin.

4.9 Amounts to be administered and administration route

Oral use.
Administration through the feed: for the preparation of a medicated feed containing 40 000 000-1 100 000 000 IU tylosine per ton of feed, the required amount of 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 product contains 250 000 000 IU tylosin it follows that 4 mg Pharmasin 250 mg/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 product per kg BW) for 3 weeks.
Broilers and pullets:
For the treatment and metaphylaxis of respiratory infections:
127 000 IU tylosin per kg BW (corresponding to 508 mg 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 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 provide the required amount of active substance in mg per kg mixed feed the following calculation should be made:

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

The mixing should be performed by an (authorised) feeding stuff manufacturer with adequate mixing apparatus.
The uptake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of tylosin should be adjusted accordingly.

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

Body weight should be evaluated accurately to avoid under dosing.

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

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.

4.11 Withdrawal period(s)

Meat & offal
Pig: Zero days
Broilers and pullets: 1 day
Do not use in laying hens producing eggs for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL 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. at concentrations of 16µg/ml or less.

5.2 Pharmacokinetic particulars

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.

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 incorporation into meal or pelleted feed: 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.
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.

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

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

7 MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

8 MARKETING AUTHORISATION NUMBER(S)

VPA10782/006/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 August 2009
Date of last renewal: 21 February 2014

10 DATE OF REVISION OF THE TEXT

September 2020