

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**Pharmasin 250 mg/g Premix** for medicated feeding stuff for pigs, broilers and pullets

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Tylosine (as tylosin phosphate) : 250 mg per g. (equivalent to 250 000 IU)

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 prevention 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 prevention of respiratory infections caused by *Mycoplasma gallisepticum* and *Mycoplasma synoviae*, when the disease has been diagnosed in the flock.
- Treatment and prevention 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

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SUMMARY OF PRODUCT CHARACTERISTICS

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**Pharmasin 250 mg/g Premix**

Huvepharma NV

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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

##### 4.5.1 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.

##### 4.5.2 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 interaction**

Lincosamides and aminoglycoside antibiotics antagonize the activity of tylosin.

**4.9 Amount(s) to be administered and administration route**

Administration through the feed: for the preparation of a medicated feed containing 40-1100 gram 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 g tylosin activity it follows that 4 mg Pharmasin 250 mg/g premix corresponds to 1 mg tylosin activity. The dosages are as follows:

Pigs

For the treatment and prevention of porcine intestinal adenomatosis (PIA):

4 – 5 mg tylosin per kg BW (corresponding to 16 - 20 mg product per kg BW) for 3 weeks.

Broilers and pullets:

For the treatment and prevention of respiratory infections:

127 mg tylosin per kg BW (corresponding to 508 mg product per kg BW) for the first 5 days of life. It is strongly recommended to repeat the treatment of the birds at the age of 3-4 weeks.

For the treatment and prevention of necrotic enteritis:

10 – 20 mg 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:

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

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**

#### **ATC Vet Code:**

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 properties**

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

### **6.5 Nature and composition of immediate packaging**

Low-density polyethylene / paper – paper - paper bag of 5 and 20 kg with sutured crimp.  
1 kg polyethylene/aluminium foil/polyethylene terephthalate sachet

Not all packs 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**

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

**7.1      MARKETING AUTHORISATION HOLDER**

Huvepharma NV  
Uitbreidingstraat 80  
2600 Antwerpen  
Belgium

**8.        MARKETING AUTHORISATION NUMBER(S)**

**9.        DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

**10.      DATE OF REVISION OF THE TEXT**

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

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

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SUMMARY OF PRODUCT CHARACTERISTICS

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**Pharmasin 250 mg/g Premix**

Huvepharma NV

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**LABEL**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**Pharmasin 250 mg/g Premix** for medicated feeding stuff for pigs, broilers and pullets  
Tylosin

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Tylosin activity (as tylosin phosphate): 250 g per kg (equivalent to 250 000 IU).

**3. PHARMACEUTICAL FORM**

Premix for medicated feeding stuff

**4. PACKAGE SIZE**

1kg  
5 kg  
20 kg

**5. TARGET SPECIES**

Pigs, broilers and pullets

**6. INDICATION(S)**

See package leaflet

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

To be administered through the medicated feed  
Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

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

**9. SPECIAL WARNING(S), IF NECESSARY**

**User Warnings**

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

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SUMMARY OF PRODUCT CHARACTERISTICS

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**Pharmasin 250 mg/g Premix**

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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.

**10. EXPIRY DATE**

<EXP {month/year}>

Shelf life after incorporation into meal or pelleted feed: 3 months

**11. SPECIAL STORAGE CONDITIONS**

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

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read the package insert.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only  
to be supplied only on veterinary prescription

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Huvepharma NV  
Uitbreidingstraat 80  
2600 Antwerpen  
Belgium

**16. MARKETING AUTHORISATION NUMBER(S)**

**17. MANUFACTURER’S BATCH NUMBER**

<Batch> <Lot> <BN> {number}

**PACKAGE LEAFLET**

**Pharmasin 250 mg/g Premix** for medicated feeding stuff for pigs, broilers and pullets

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder

Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerpen, Belgium

Manufacturer for batch release

Biovet JSC, 39 Petar Rakov Str, 4550 Peshtera - Bulgaria

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**Pharmasin 250 mg/g Premix** for medicated feeding stuff for pigs, broilers and pullets  
Tylosin

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

Tylosin (as tylosin phosphate) : 250 mg per g.

Light tan coloured, free flowing granules.

**4. INDICATION(S)**

Pigs

- Treatment and prevention of Porcine Intestinal Adenomatosis (PIA) associated with *Lawsonia intracellularis* when the disease has been diagnosed at the group or herd level,

Broilers and pullets:

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

**5. 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

## 6. ADVERSE REACTIONS

In pigs, adverse reactions have been observed, including diarrhoea, pruritus, erythema, rectal oedema and prolapse. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon

## 7. TARGET SPECIES

Pigs, broilers and pullets.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Administration through the feed: for the preparation of a medicated feed containing 40-1100 gram tylosine per ton of feed, the required amount of Pharmasin 250 mg/g Premix 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 Pharmasin 250 mg/g premix contains 250 g tylosin activity it follows that 4 mg Pharmasin 250 mg/g premix corresponds to 1 mg tylosin activity. The dosages are as follows:

### Pigs

For the treatment and prevention of porcine intestinal adenomatosis (PIA):

4 – 5 mg tylosin per kg BW (corresponding to 16 - 20 mg Pharmasin 250 mg/g premix per kg BW) for 3 weeks.

### Broilers and pullets

For the treatment and prevention of respiratory infections:

127 mg tylosin per kg BW (corresponding to 508 mg Pharmasin 250 mg/g premix per kg BW) for the first 5 days of life. It is strongly recommended to repeat the treatment of the birds at the age of 3-4 weeks.

For the treatment and prevention of necrotic enteritis:

10 – 20 mg tylosin per kg BW (corresponding to 40 – 80 mg Pharmasin 250 mg/g premix 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:

.... mg Pharmasin 250 mg/g                      average body weight (kg)

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$$\frac{\text{premix /kg BW/day}}{\text{Average daily amount of mixed feed intake /kg per animal}} \times \text{of the animals to be treated} = \dots \text{ mg Pharmasin}$$
$$250 \text{ mg/g premix per kg/ mixed feed}$$

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

### 9. ADVICE ON CORRECT ADMINISTRATION

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

### 10. WITHDRAWAL PERIOD

Meat & offal

Pig: Zero days

Broilers and pullets: 1 day

Do not use in laying hens producing eggs for human consumption.

### 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf life after incorporation into meal or pelleted feed : 3 months

### 12. SPECIAL WARNING(S)

#### **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.

#### **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

#### **Interaction with other medicinal products and other forms of interaction**

Lincosamides and aminoglycoside antibiotics antagonize the activity of tylosin

#### **Overdose**

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

#### **Incompatibilities**

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

### **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

**15. OTHER INFORMATION**

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Low-density polyethylene / paper – paper - paper bag of 5 and 20 kg with sutured crimp.  
1 kg polyethylene/aluminium foil/polyethylene terephthalate sachet.

Not all pack sizes may be marketed.