PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {5 kg – 20 kg bag}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pharmasin 100 000 IU/g Premix for medicated feeding stuff for pigs, broilers and pullets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each gram contains:

Active substance:

Tylosin (as tylosin phosphate): 100 000 IU

Excipients:
Dipotassium phosphate (E340)

3. PACKAGE SIZE

5 kg
20 kg

4. TARGET SPECIES

Pigs, chickens (broilers and pullets).

5. INDICATIONS

See package leaflet

6. ROUTES OF ADMINISTRATION

To be administered through the medicated feed.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

<Exp {mm/yyyy}>
Shelf life after incorporation into meal or pelleted feed: 3 months.

9. SPECIAL STORAGE PRECAUTIONS

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.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

14. MARKETING AUTHORISATION NUMBER

Vm 30282/5008

15. BATCH NUMBER

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

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
POM-V Veterinary medicinal product subject to prescription

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pharmasin 100 000 IU/g Premix for medicated feeding stuff for pigs, broilers and pullets

2. COMPOSITION

Each gram contains:

Active substance:
Tylosin (as tylosin phosphate): 100 000 IU

Excipients:
Dipotassium phosphate (E340)

Light tan coloured, free flowing granules

3. TARGET SPECIES

Pigs, chickens (broilers and pullets) .

4. INDICATIONS FOR USE

Pigs

- Treatment and metaphylaxis of Porcine Intestinal Adenomatosis (PIA) 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.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to tylosin, 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.

6. SPECIAL WARNINGS

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 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.

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.

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.

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.

Special restrictions for use and special conditions for use:

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.

Major incompatibilities:

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

7. ADVERSE EVENTS

Pigs:

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

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

Oral use.

Administration through the feed: for the preparation of a medicated feed containing 40 000 000-200 000 000 IU tylosin per ton of feed, the required amount of Pharmasin 100 mg/g 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 100 000 000 IU tylosin it follows that 10 mg Pharmasin 100 000 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 40-50 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 1270 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 100 – 200 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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIODS

Meat & offal.

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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.

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 PRECAUTIONS FOR DISPOSAL

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 30282/5008

Bag of 5 kg
Bag of 20 kg

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

October 2023

16. CONTACT DETAILS

Marketing authorisation holder <and contact details to report suspected adverse reactions>
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium
+32 3 288 18 49
pharmacovigilance@huvepharma.com

Manufacturer responsible for batch release
Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

<Local representatives and contact details to report suspected adverse reactions>

17. OTHER INFORMATION

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

Approved: 20 February 2024