LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each g contains:

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

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff

4. PACKAGE SIZE

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: 0 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 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 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.

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 THESIGHT 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)

Vm 30282/4007

17. MANUFACTURER'S BATCH NUMBER

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

PACKAGE LEAFLET

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

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

Each g contains:

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

Light tan coloured, free flowing granules

4. INDICATION(S)

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.

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 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 hypersensitivity 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

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 Pharmasin 100 mg/g premix contains 100 000 000 IU tylosin it follows that 10 mg Pharmasin 100 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 40-50 mg Pharmasin 100 mg/g premix 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 1270 mg Pharmasin 100 mg/g premix 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 Pharmasin 100 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:

$$\frac{\text{…. mg Pharmasin 100 mg/g premix /kg BW/day} \times \text{average body weight (kg) of the animals to be treated}}{\text{Average daily amount of mixed feed intake /kg per animal}} = \text{… mg Pharmasin 100 mg/g premix per kg/ mixed feed}$$

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: 0 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 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 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 fo 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

May 2020

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 with sutured crimp.

Pack sizes:
Bag of 5 kg
Bag of 20 kg

Not all pack sizes may be marketed.

Approved 02 July 2020