LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pharmasin 20 000 IU/g Oral Granules for pigs
Tylosin phosphate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each g contains:

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

3. PHARMACEUTICAL FORM

Granules

4. PACKAGE SIZE

1 kg
5 kg

5. TARGET SPECIES

Pigs.

6. INDICATION(S)

See package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral administration to the individual pig.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Pigs (meat): 1 day

9. SPECIAL WARNING(S), IF NECESSARY

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

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 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 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}>
Once opened, use by:
Shelf-life after first opening the immediate packaging: 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 leaflet.

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)

Vm 30282/4010

17. MANUFACTURER'S BATCH NUMBER

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

PACKAGE LEAFLET

Pharmasin 20 000 IU/g Oral Granules for pigs

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

Marketing authorisation

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 20 000 IU/g Oral Granules for pigs
Tylosin phosphate

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

Each g contains:

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

Light tan coloured, free flowing granules.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to the active substance and/or to any of the excipients of the 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.

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

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 Pharmasin 2% Oral Granules/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.

The pig to be treated should be weighed to prevent under dosing.

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

9. ADVICE ON CORRECT ADMINISTRATION

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 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

Pigs (meat): 1 day.

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 first opening the immediate packaging: 3 months.

12. SPECIAL WARNING(S)

Special precautions for the person administering the veterinary medicinal product to animals

Tylosin may induce irritation. Macrolides, such as 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 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 or lactation

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**.**

Interaction with other medicinal products and other forms of interaction

Lincosamides and aminoglycoside antibiotics antagonize the activity of tylosin.

Overdose

The 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.

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.

When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label

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.

Approved 02 July 2020