PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {1 kg – 5 kg bag}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pharmasin 20 000 IU/g Oral Granules

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each gram contains:

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

Excipients:
Dipotassium phosphate (E340)

3. PACKAGE SIZE

1 kg
5 kg

4. TARGET SPECIES

Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral administration to the individual pig.

7. WITHDRAWAL PERIODS

Pigs

Meat and offal: 1 day.

8. EXPIRY DATE

<Exp {mm/yyyy}>
Once opened, use by:
Once opened, use within 3 months. Use by…

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 30282/5010

15. BATCH NUMBER

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

16. 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 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.

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

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE *[Distribution category]* POM-V Veterinary medicinal product subject to prescription

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pharmasin 20 000 IU/g Oral Granules for pigs

2. COMPOSITION

Each gram contains:

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

Excipients:
Dipotassium phosphate (E340)

Light tan coloured, free flowing granules

3. TARGET SPECIES

Pigs.

4. INDICATIONS FOR USE

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 cases of hypersensitivity to the active substance, 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:

This veterinary medicinal 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 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 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 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:

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.

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.

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 veterinary medicinal product/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 veterinary medicinal product should be added to the estimated quantity of daily ration for each pig in a bucket or similar receptacle and thoroughly mixed. The veterinary medicinal product should only be added to dry non-pelleted feed.

To ensure a correct dosage, body weight should be determined as accurately as possible

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

9. ADVICE ON CORRECT ADMINISTRATION

This veterinary medicinal 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 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

Pigs

Meat and offal: 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 this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Once opened, use within 3 months. Use by…

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

Low-density polyethylene / paper-paper-paper bag with sutured crimp.

Vm 30282/5010

<u>Pack sizes:</u>
Bag of 1 kg
Bag of 5 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 Antwerpen
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>

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

17. OTHER INFORMATION

Approved 21 February 2024