PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Resealable 1.1 kg PE-Alu-PET bag}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pharmasin 1g/g Granules for Use in Drinking Water
for Pigs, Chickens, Turkeys and Calves

Tylosin (as Tylosin tartrate)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1.1 g of granules contains
Active substance:
1000 mg of tylosin (equivalent to 1100 mg of tylosin tartrate)

3. PACKAGE SIZE

1.1 kg
110 g

4. TARGET SPECIES

Pigs, chickens, turkeys and calves

5. INDICATIONS

Read the package leaflet before use.

6. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

7. WITHDRAWAL PERIODS

Calves (meat and offal): 12 days
Pigs (meat and offal): 1 day
Turkeys (meat and offal): 2 days
Turkey (eggs): Zero days
Chickens (meat and offal): 1 day
Chicken (eggs): Zero days

8. EXPIRY DATE

Exp {mm/yyyy}
Shelf life after dilution or reconstitution in water, milk or milk replacer: 24 hours.
Shelf life after first opening the immediate pakaging: 3 months.
Once broached, use by:

9. SPECIAL STORAGE PRECAUTIONS

Store in the original container in order to protect from light.
Store below 30° C.

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

14. MARKETING AUTHORISATION NUMBER

Vm 30282/5006

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNINGS, IF NECESSARY

Do not use in cases of hypersensitivity/ resistance to tylosin or in cases of cross-resistance to other macrolides.
Read the package leaflet for full instructions and user warnings before use.

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

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pharmasin 1g/g Granules for Use in Drinking Water for Pigs, Chickens, Turkeys and Calves

2. COMPOSITION

Each 1.1 g of granules contains
Active substance:
1000 mg of tylosin (equivalent to 1100 mg of tylosin tartrate)
White to light yellow coloured granules.

3. TARGET SPECIES

Calves, pigs, chickens, turkeys

4. INDICATIONS FOR USE

Calves: Treatment and prevention of pneumonia caused by *Mycoplasma spp* when the disease has been established in the herd
Pigs:
- Treatment and prevention of enzootic pneumonia caused by *Mycoplasma hyopneumoniae* and *Mycoplasma hyorhinis* when the when the disease has been established in the herd.
- Treatment and prevention of Porcine Intestinal Adenomatosis (Ileitis) associated with *Lawsonia intracellularis* when the disease has been established in the herd.

Chickens:
- Treatment and prevention of chronic respiratory diseases (CRD) caused by *Mycoplasma gallisepticum* and *Mycoplasma synoviae* when the disease has been established in the flock
- Treatment and prevention of necrotic enteritis caused by *Clostridium perfringens* when the disease has been established in the flock

Turkeys: Treatment and prevention of infectious sinusitis caused by *Mycoplasma gallisepticum.* when the disease has been established in the flock.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to tylosin or other macrolides,
Do not use in cases with known resistance to tylosin or cross-resistance to other macrolides (MLS-resistance).
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 because of danger for inflammation of the caecum.

6. SPECIAL WARNINGS

Special warnings:

Due to likely variability (time, geographical) in susceptibility of bacteria to tylosin, bacteriological sampling and susceptibility testing are recommended.

Under-dosing and/or treating for an insufficient length of time are considered to promote the development of resistance in bacteria and should be avoided.

Special precautions for safe use in the target species:

Animals with acute infections may have a reduced water and feed intake and should be treated with a suitable injectable veterinary medicinal product first.

Do not leave or dispose of water containing tylosin tartrate where it may be accessible to either animals not under treatment or wildlife.

Special precautions to be taken by 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 preparation of the medicated Tylosin may induce irritation. Macrolides, such as tylosin, may also cause hypersensitivity (allergy) following drinking water, 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.

Pregnancy and lactation:

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. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interactions with other medicinal products and other forms of interaction:

Lincosamides and aminoglycoside antibiotics antagonize the activity of tylosin.

Overdose:

There is no evidence of tylosin toxicity in rats, at dose rates of up to 1000 mg/kg by the oral route.There is no evidence of tylosin toxicity in chickens, turkeys, pigs or calves when administered orally at up to three times the recommended dose. Lincosamides and aminoglycoside antibiotics antagonize the activity of tylosin.

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 the available data)	Diarrhoea*, pruritus (itching)*, reddening of the skin (erythema)*, swollen vulva*, rectal oedema (swelling)* and rectal prolapse*

* all transient and appear 48-72 hours after start of the treatment

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 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 administration through the drinking water
In calves the product can also be administered through milk or milk replacer.

1.1 gram of the veterinary medicinal product corresponds to 1 gram of tylosin. The dosages are as follows:

Calves:
10 – 20 mg tylosin per kg BW (corresponding to 11 – 22 mg of the veterinary medicinal product per kg BW), twice daily (corresponding to a daily dose of 20 – 40 mg tylosin per kg BW), for 7 - 14 days.

Turkeys:
75 – 100 mg tylosin per kg BW per day (corresponding to 82.5 – 110 mg of the veterinary medicinal product per kg BW) for 3 – 5 days.

Chickens:
For the treatment of chronic respiratory disease:
75 – 100 mg tylosin per kg BW per day (corresponding to 82.5 – 110 mg of the veterinary medicinal product per kg BW) for 3 – 5 days.

For the treatment of necrotic enteritis:
20 mg tylosin per kg BW per day (corresponding to 22 mg of the veterinary medicinal product) for 3 days.

Pigs:
For the treatment of enzootic pneumonia:
20 mg tylosin per kg BW per day (corresponding to 22 mg of the veterinary medicinal product per kg BW) for 10 days.
For the treatment of ileitis or PIA:
5 – 10 mg tylosin per kg BW per day (corresponding to 5.5 - 11 mg of the veterinary medicinal product per kg BW) for 7 days.

For the preparation of the medicated water/milk/milk-replacer the body weight of the animals to be treated and their actual daily water/milk/milk-replacer consumption should be taken into due account. Consumption may vary depending on factors like age, state of health, breed, husbandry system. To provide the required amount of active substance in mg per litre drinking water/milk/milk-replacer the following calculation should be made:

$$\frac{\text{…… mg tylosin per kg bodyweight per day} \times \text{Average bodyweight (kg) of the animals to be treated}}{\text{Average amount of drinking water or milk / animal (l)}} = \text{……mg tylosin / l of drinking water}$$

Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. No other source of drinking water should be available during the medication period.

Should there be no clear response to treatment within 3 days the treatment approach should be reconsidered. After the end of the medication period the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance which might support development of resistance.
Medicated water, milk or milk replacer should be replaced every 24 hours.
If individual animals show signs of a serious infection such as a reduced water or feed intake, then they should be treated individually, such as by injection.

9. ADVICE ON CORRECT ADMINISTRATION

Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. No other source of drinking water should be available during the medication period.
Should there be no clear response to treatment within 3 days the treatment approach should be reconsidered. After the end of the medication period the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance which might support development of resistance.
Medicated water, milk or milk replacer should be replaced every 24 hours.

10. WITHDRAWAL PERIODS

Calves (meat and offal): 12 days
Pigs (meat and offal): 1 day
Turkeys (meat and offal): 2 days
Turkey (eggs): Zero days
Chickens (meat and offal): 1 day
Chicken (eggs): Zero days

11. SPECIAL STORAGE PRECAUTIONS

Store in the original container in order to protect from light. Store below 30°C.
Shelf-life after dilution or reconstitution according to directions:
medicated water:24 hours
medicated milk or milk replacer:24 hours
Shelf-life after first opening the immediate packaging: 3 months
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Once the immediate package is opened, using the shelf-life after first opening, calculate the discard date and record in the space provided. Keep out of the sight and reach of children.

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

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 30282/5006

1.1 kg resealable block bottom zipped sachet made of polyethylene /aluminium/polyethylene terephthalate laminate
110 g high density polyethylene pot with polypropylene cap

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

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

Contact details to report suspected adverse reactions
Ellie Radford
e-mail: ellie.radford@huvepharma.com

17. OTHER INFORMATION

Approved