B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Tylmasin 250 000 IU/g premix for medicated feeding stuff for pigs and chickens (ES & IT)
Pharmasin 250 000 IU/g premix for medicated feeding stuff for pigs and chickens (PT)

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

For IT & PT:

Marketing authorisation holder:
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

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

For ES:

Marketing authorisation holder and manufacturer responsible for batch release:
Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylmasin 250 000 IU/g premix for medicated feeding stuff for pigs and chickens (ES & IT)
Pharmasin 250 000 IU/g premix for medicated feeding stuff for pigs and chickens (PT)
Tylosin phosphate

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

Each g contains:

Active substance:
Tylosin (as tylosin phosphate)..... 250 000 IU

Excipients:
Wheat meal
Other excipients, q.s.

Off white to beige granules.

4. INDICATION(S)

Pigs: Treatment and metaphylaxis of enzootic pneumonia caused by *Mycoplasma hyopneumoniae,* atrophic rhinitis and Porcine Proliferative Enteropathy caused by *Lawsonia intracellularis.*

Chickens: Treatment and metaphylaxis of Chronic Respiratory Disease (CRD) caused by *Mycoplasma gallisepticum* or *M. synoviae*, necrotic enteritis caused by *Clostridium perfringens*, sensitive to tylosin

The presence of the disease in the group should be confirmed before metaphylactic treatment

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 hyper sensitivity 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 one 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 in very rare cases.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Pigs, Chickens.

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

In feed use.

Pigs:
Treatment and metaphylaxis of enzootic pneumonia caused by *Mycoplasma hyopneumoniae*, atrophic rhinitis, and Porcine Proliferative Enteropathy caused by *Lawsonia intracellularis:*
3000 – 6000 IU tylosin per kg bw (corresponding to 12-24 mg product per kg bw), used as the sole ration for 21 days. Treatment duration should not exceed 3 weeks.

Chickens :
Treatment and metaphylaxis of Chronic Respiratory Disease (CRD) caused by *Mycoplasma gallisepticum* or *M. synoviae:*
In broiler chickens and replacement pullets: 127 000 IU tylosin per kg bw (corresponding to 508 mg product per kg bw) during the first five days of age followed by a second treatment at the age of 3-5.
In laying hens: 50 000 IU tylosin per kg bw (corresponding to 200 mg product per kg bw) for 5 days.

Treatment and metaphylaxis of necrotic enteritis caused by *Clostridium perfringens*, sensitive to tylosin: 10 000 – 20 000 IU tylosin per kg bw (corresponding to 40-80 mg product per kg bw) for 7 days.

9. ADVICE ON CORRECT ADMINISTRATION

All species:
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, and husbandry system. To provide the required amount of active substance in mg per kg mixed feed the following calculation should be made:

Dose (mg/kg BW) X Average body weight (kg) of the animals to be treated = kg product
Average daily feed intake (kg per animal) X Premix concentration (g/kg) per ton mixed feed

Instructions for mixing:
Mix the required dose of product in a small quantity of feed (20-25 kg) before incorporating into the final amount of feed.

10. WITHDRAWAL PERIOD

Pigs	Meat and offal: Zero days
Chickens	Meat and offal: Zero days
	Eggs: Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in the original container to protect from light.
Store in a dry place.
Store below 30°C.
Do not refrigerate or freeze.
Protect from frost

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 on that month.

Shelf-life after first opening the immediate packaging: 3 months
Shelf life after incorporation into meal or pelleted feed : 2 months.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Animals with acute infections may have a reduced feed intake and should be treated with a suitable injectable product first.

Special precautions for use in animals:
Mix well with feed to ensure good distribution.
Whenever possible, the product should only be used based on susceptibility testing.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to Tylosin and other Macrolides.

Special precautions to be taken by 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.
People with known hypersensitivity to macrolides or the excipients of the product should avoid contact with the veterinary medicinal product.
To avoid exposure during mixing, 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 when handling the veterinary medicinal product.
Wash hands after use.
In case 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.
If you develop symptoms following exposure, such as skin rash, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

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:
Florfenicol, lincosamides and other macrolides, which have an action similar to tylosin could interact by competing for binding to the 50S subunit, so it is not recommended for use simultaneously.

Overdose (symptoms, emergency procedures, antidotes):
Tylosin has a wide margin of tolerance in pigs and chickens when administered orally. Tylosin has been shown to produce no adverse effects when fed to pigs at 600 ppm in the feed (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.

Other precautions

Tylosin is toxic for plants. The poultry litter coming from treated animals should not be used as fertilizer without being mixed with at least the same amount of litter coming from untreated animals.

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

15. OTHER INFORMATION

Low density polyethylene inner lined multi-walled paper bag with sutured crimp.
Polyethylene/aluminium foil/polyethylene terephthalate sachet

Pack sizes:
Sachet of 1 kg
Bag of 5 kg
Bag of 20 kg

Not all pack sizes may be marketed.

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

ES only:
For animal treatment only – to be supplied only on veterinary prescription.
To be administered by the veterinarian or under veterinarian supervision.