

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**Low density polyethylene inner lined multi-walled paper bag or Polyethylene/aluminium foil/polyethylene terephthalate sachet**

**1. 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

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each g contains:

**Active substance:**

Tylosin (as tylosin phosphate): 250 000 IU

**3. PHARMACEUTICAL FORM**

Premix for medicated feeding stuff

**4. PACKAGE SIZE**

1kg  
5 kg  
20 kg

**5. TARGET SPECIES**

Pigs, Chickens

**6. 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

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

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

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

Once opened use within: 3 months

Once reconstituted use within: 2 months

**11. SPECIAL STORAGE CONDITIONS**

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.

**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.

Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

**For ES:** To be administered by the veterinarian or under veterinarian supervision.

**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**

**16. MARKETING AUTHORISATION NUMBER(S)**

**17. MANUFACTURER’S BATCH NUMBER**

<Batch><Lot> {number}