ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Polyethylene naphthalate amber coloured bottle with a polypropylene screw top and polyethylene/aluminium/polyethylene terephthalate seal

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pulmotil AC 250 mg/mL concentrate for oral solution for use in drinking water or milk replacer for chickens, turkeys, pigs and calves
Tilmicosin

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance: Tilmicosin (as phosphate) 250 mg/mL.
Excipients: propyl gallate**,** disodium edetate.

3. PHARMACEUTICAL FORM

Concentrate for oral solution for use in drinking water or milk replacer.

4. PACKAGE SIZE

240 mL
960 mL

5. TARGET SPECIES

Chickens (except hens producing eggs for human consumption)
Pigs
Turkeys
Calves (pre-ruminant)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet on reverse of the label before use.
For oral use in drinking water or milk replacer.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Pigs: Meat and offal: 14 days
Chickens: Meat and offal: 12 days
Turkeys: Meat and offal: 19 days
Calves: Meat and offal: 42 days
Not authorised for use in animals producing milk for human consumption.
Not authorised for use in laying birds producing eggs for human consumption.
Do not use within 14 days of onset of the laying.

9. SPECIAL WARNING(S), IF NECESSARY

Important: Must be diluted before administration to animals.
For oral use only. Do not inject.
Do not allow horses and other equines access to drinking water containing tilmicosin.
People with known hypersensitivity to active substance should avoid contact with the product.
When mixing the veterinary medicinal product direct contact with eyes, skin and mucous membranes
should be avoided. Personal protective equipment should be worn.
In case of accidental ingestion seek medical advice immediately and show the label to the physician.

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 3 months.
Once reconstituted in drinking water, use within 24 hours.
Once reconstituted in milk replacer, use within 6 hours.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.
Do not refrigerate or freeze. Protect from frost. Protect from sunlight.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

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

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/5085

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Pulmotil AC 250 mg/ml Concentrate for Oral Solution for Use in Drinking Water or Milk Replacer

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

Marketing authorisation holder:
Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Manufacturer responsible for batch release:
Elanco UK AH Limited
Fleming Road
Speke
Liverpool, Merseyside
L24 9LN
United Kingdom

Elanco France
26 Rue de la Chapelle
68330 Huningue
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pulmotil AC 250 mg/mL Concentrate for Oral Solution for Use in Drinking Water or Milk Replacer

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

Active substance: Tilmicosin (as phosphate) 250 mg/mL
Excipients: propyl gallate, disodium edetate
Clear yellow to amber coloured solution.

4. INDICATION(S)

Pigs: For the treatment and metaphylaxis of respiratory disease, associated with *Mycoplasma hyopneumoniae, Pasteurella multocida, Actinobacillus pleuropneumoniae* susceptible to tilmicosin.

Chickens: For the treatment and metaphylaxis of respiratory disease, associated with *Mycoplasma gallisepticum* and *M. synoviae* susceptible to tilmicosin.

Turkeys: For the treatment and metaphylaxis of respiratory disease, associated with *Mycoplasma gallisepticum* and *M. synoviae* susceptible to tilmicosin.

Calves: For the treatment and metaphylaxis of bovine respiratory disease, associated with *Mannheimia haemolytica, Pasteurella multocida, Mycoplasma bovis, M. dispar* susceptible to tilmicosin.

The presence of the disease in the group/flock must be established before the product is used.

5. CONTRAINDICATIONS

Do not allow horses and other equines access to drinking water containing tilmicosin.
Do not use in known cases of hypersensitivity to active substance or to any of the excipients.
Do not use in ruminants with active rumen function.

6. ADVERSE REACTIONS

In very rare cases, a decrease in water intake has been observed.

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.

Alternatively, you can report via your national reporting system.

7. TARGET SPECIES

Chickens (except hens producing eggs for human consumption)
Turkeys
Pigs
Calves (pre-ruminant)

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

For oral use only. The veterinary medicinal product must be diluted in drinking water (pigs, chickens, turkeys) or milk replacer (calves) before administration.

Pigs: To be included in the drinking water to provide a daily dose of 15-20 mg/kg bodyweight for 5 days, which may be achieved by the inclusion of 200 mg tilmicosin per litre (80 mL of veterinary medicinal product per 100 litres).

Chickens and Turkeys (except hens producing eggs for human consumption): To be included in the drinking water at a daily dose of 15-20 mg/kg bodyweight in chickens and 10-27 mg/kg bodyweight in turkeys for 3 days, which may be achieved by the inclusion of 75 mg tilmicosin per litre (30 mL of veterinary medicinal product per 100 litres).

Calves: To be included in milk replacer only, at a dose of 12.5 mg/kg bodyweight and given twice daily for 3-5 consecutive days, which may be achieved by the inclusion of 1 mL of product every 20 kg bodyweight.

One 240 mL bottle of veterinary medicinal product is sufficient to medicate 300 litres of drinking water for pigs or 800 litres of drinking water for chickens or turkeys. One 960 mL bottle is sufficient to medicate 1200 litres of drinking water for pigs or 3200 litres of drinking water for chickens or turkeys.

One 240 mL bottle and 960 mL bottle of veterinary medicinal product are sufficient to medicate in milk replacer respectively 12 to 20 and 48 to 80 veal calves each of 40 kg bodyweight depending on the duration of treatment.

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid under-dosing.
The required dose should be measured using suitably calibrated measuring equipment.
Only sufficient medicated drinking water should be prepared to cover the daily requirements.
The medicated water should be the only source of drinking water for animals for the entire duration of the treatment period.
Water intake should be monitored at frequent intervals during treatment period.
After the end of the treatment phase, the water supply system should be thoroughly cleaned to avoid intake of sub-therapeutic amounts of the active substance.
Medicated drinking water should be prepared freshly every 24 hours.
Medicated milk replacer should be prepared freshly every 6 hours.

The uptake of medicated drinking water/milk replacer depends on the clinical condition of the animals. In order to obtain a correct dosage the concentration of tilmicosin should be adjusted accordingly.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Pigs:
Meat and offal: 14 days
Chickens:
Meat and offal: 12 days
Turkeys: Meat and offal: 19 days
Calves:
Meat and offal: 42 days

Not authorised for use in animals producing milk for human consumption.
Not authorised for use in laying birds producing eggs for human consumption.

Do not use within 14 days of the start of the laying period.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 30 °C.
Do not refrigerate or freeze. Protect from frost. Protect from sunlight.

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.

Shelf life after first opening the container: 3 months.
Shelf life after reconstitution in drinking water: 24 hours.
Shelf life after reconstitution in milk replacer: 6 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Important: Must be diluted before administration to animals.
The uptake of veterinary medicinal products can be altered in animals as a consequence of an illness. In case of insufficient uptake of water or milk replacer, the animals should be treated parenterally using an appropriate injectable product.
Repeated use of the veterinary medicinal product should be avoided by improving management practices and thorough cleansing and disinfection.
Pigs, chickens and turkeys: Water consumption should be monitored in order to guarantee adequate dosing. In case water consumption does not match quantities for which recommended concentrations were calculated, the concentration of veterinary medicinal product has to be adapted in a way that the recommended dosage will be taken up by the animals or different medication should be considered.

Special precautions for use in animals:
For oral use only. Contains disodium edetate; do not inject.

Use of the veterinary medicinal product should be based on the susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Use of the veterinary medicinal product deviating from instructions given in the SPC may increase the prevalence of bacteria resistant to tilmicosin and may decrease the effectiveness of treatment with other macrolides, lincosamides and streptogramin B due to the potential cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
- Tilmicosin may induce irritation. Macrolides, such as tilmicosin, may also cause hypersensitivity (allergy) following injection, inhalation, ingestion or contact with skin or eye. Hypersensitivity to tilmicosin 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 drinking water, wear overalls, safety glasses, and impervious gloves. Do not eat, drink or smoke when handling this product. Wash hands after use.
- In the case of accidental ingestion, wash out mouth immediately with water and seek medical advice. 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, lay:
The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay.
Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with other macrolides and lincosamides.
Do not use simultaneously with bacteriostatic antimicrobial agents.
Tilmicosin may lessen the antibacterial activity of β-lactam antibiotics.

Overdose (symptoms, emergency procedures, antidotes):
When pigs are offered drinking water containing 300 or 400 mg/litre (equivalent to 22.5-40 mg/kg bodyweight or 1.5-2 times the recommended concentration) commonly animals exhibit a reduced water intake. Although this has a self-limiting effect on tilmicosin intake, it could, in extreme circumstances, result in dehydration. This can be corrected by the removal of the medicated drinking water and replacement with fresh unmedicated water.
No symptoms of overdose have been seen in chickens given drinking water containing levels of tilmicosin up to 375 mg/litre (equivalent to 75-100 mg/kg bodyweight or 5 times the recommended dose) for 5 days; daily treatment with 75 mg/litre (equivalent to the maximum recommended dose) for 10 days resulted in softer faecal consistency.

No symptoms of overdose have been seen in turkeys given drinking water containing levels of tilmicosin up to 375 mg/litre (equivalent to 50-135 mg/kg bodyweight or 5 times the recommended dose) for 3 days; daily treatment with 75 mg/litre (equivalent to the maximum recommended dose) for 6 days also produced no symptoms of overdose.

No symptoms of overdose, with exception of a slight decrease in the milk consumption, have been seen in calves given twice daily doses 5 times the

maximum recommended dose or for twice the maximum recommended duration of treatment.

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

Enviromental properties:
The active substance tilmicosin is persistent in soils. Tilmicosin is known to be toxic to aquatic organisms."

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.
Veterinary medicinal product should not enter watercourses, as this may be dangerous for fish and other aquatic organisms.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.
Manure from treated animals should not be deposited on the same field in successive years**.**

14. 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.

15. OTHER INFORMATION

The primary container is a polyethylene naphthalate amber coloured bottle containing 240 mL or 960mL of veterinary medicinal product, with a polypropylene screw top and polyethylene/aluminium/polyethylene terephthalate seal.
A graduated polypropylene cup is also supplied.
Not all pack sizes may be marketed.

Gavin Hall
Approved: 12 December 2025