APPENDIX B:

LABELLING

<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>
COMBINED LABEL AND PACKAGE LEAFLET

HDPE bottle/can

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Marketing authorisation holder:
Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer,
The Netherlands

Manufacturer responsible for the batch release:
Dopharma B.V.
Zalmweg 24
4941 VX Raamsdonksveer, NL

2. Name of the veterinary medicinal product

Pulmovet 250 mg/ml solution for use in drinking water or milk replacer for cattle, pigs, chickens and turkeys
Tilmicosin (as tilmicosin phosphate)

3. Statement of the active substance and other ingredients

Each ml of clear yellow to brown solution contains:
Active substance: Tilmicosin (as tilmicosin phosphate): 250 mg
Excipients: Propyl gallate (E310): 0.2 mg
Disodium edetate: 2.0 mg

4. Pharmaceutical form

Solution for use in drinking water or milk replacer.

5. Package size

960 ml

5040 ml

6. Indications

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

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.

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

7. Contraindications

Do not allow horses and other equines access to drinking water containing tilmicosin.
Do not use in case of hypersensitivity to tilmicosin or to any of the excipients.

8. Adverse reactions

In very rare cases (less than 1 animal in 10,000 animals, including isolated reports), a decrease in water intake has been observed.
If you notice any side effects or other effects, even those not already listed in this label, or you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}.

9. Target species

Cattle (pre-ruminant), pigs, chickens (except hens producing eggs for human consumption) and turkeys.

10. Dosage for each species, route and method of administration

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

Calves: 12.5 mg tilmicosin/kg body weight (i.e.1 ml of product per 20 kg BW), twice daily, for 3-5 consecutive days.

Pigs: 15-20 mg tilmicosin/kg body weight/day (i.e. 6-8 ml of product per 100 kg of BW per day),
for 5 consecutive days, which may be achieved by the inclusion of 200 mg of tilmicosin per litre (80 ml of product per 100 litres).

Chickens: 15-20 mg tilmicosin/kg body weight/day (i.e. 6-8 ml of product per 100 kg of BW per day), for 3 consecutive days, which may achieved by the inclusion of 75 mg of tilmicosin per litre (30 ml of product per 100 litres).

Turkeys: 10-27 mg tilmicosin/kg body weight/day (i.e. 4-11 ml of product per 100 kg of BW per day), for 3 consecutive days, which may achieved by the inclusion of 75 mg of tilmicosin per litre (30 ml of product per 100 litres).

The exact daily amount of the veterinary medicinal product required can be calculated according to the following formula:
ml product per litre drinking water per day = [ml product per kg bodyweight per day x average bodyweight (kg)] / average daily water intake (litre).

One 960 ml bottle of product is sufficient to medicate 1200 litres of drinking water for pigs or 3200 litres of drinking water for chickens or turkeys. One 5040 ml bottle is sufficient to medicate 6300 litres of drinking water for pigs or 16800 litres of drinking water for chickens or turkeys.

One 960 ml bottle and 5040 ml can of product are sufficient to medicate in milk replacer respectively 48 to 80 and 252 to 420 veal calves each of 40 kg bodyweight depending on the duration of treatment.

11. Advice on correct administration

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 the animals for the entire duration of the treatment period.
Water intake should be monitored at frequent intervals during medication.
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.

Medicated drinking water should be prepared fresh every 24 hours. Medicated milk replacer should be prepared fresh every 6 hours.

The medicinal product should be diluted with water or milk replacer prior to its use and the concentration of the prediluted solution should not exceed 200 ml of product/litre (i.e. 1 in 5). The lowest concentrations of the product at which stability can be assured are: 0.3 ml product/litre drinking water and 0.7 ml product/litre milk replacer.

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

12. Withdrawal period

Withdrawal periods:

Calves (meat and offal):	42 days.
Pigs (meat and offal):	14 days.
Chickens (meat and offal):	12 days.
Turkeys (meat and offal):	19 days.

Not authorised for use in animals producing milk for human consumption.
Not authorised for use in birds producing eggs for human consumption.
Do not use within 2 weeks of the start of the laying period.

13. Special storage precautions

Store below 25ºC. Do not refrigerate or freeze. Protect from frost. 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.

14. Special warnings

Special precautions for use in animals
For oral use only. Contains disodium edetate; do not inject.
Use of the product should be based on 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 product deviating from the 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 for cross-resistance.
Official, national and regional antimicrobial policies should be taken into account when the product is used.

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 or milk replacer, 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, lactation or 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
Tilmicosin may lessen the antibacterial activity of beta-lactam antibiotics.
Do not use simultaneously with bacteriostatic antimicrobial agents.

Overdose (symptoms, emergency procedures, antidotes)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.
When pigs are offered drinking water containing 300 or 400 mg tilmicosin/litre (equivalent to 22.5-40 mg tilmicosin/kg body weight 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 tilmicosin/kg body weight or 5 times the recommended dose) for 5 days; daily treatment with 75 mg tilmicosin/litre (equivalent to the maximum recommended dose) for 10 days resulted in a reduction in 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 tilmicosin/kg body weight or 5 times the recommended dose) for 3 days; daily treatment with 75 mg tilmicosin/litre (equivalent to the maximum recommended dose) for 6 days also produced no symptoms of overdose.

15. Special precautions for the disposal of unused products or waste materials, if any

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Veterinary medicinal product must not be disposed of via waste water or the drainage systems.

16. Date on which the package leaflet was last approved

17. Other information

List of pack sizes:
- Bottle of 960 ml
- Can of 5040 ml

Not all pack sizes may be marketed.

18. 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

19. The words "keep out of the sight and reach of children"

Keep out of the sight and reach of children.

20. Expiry date

EXP << >>

Shelf life after first opening the container: 3 months
Shelf-life after dilution in drinking water according to instructions: 24 hours
Shelf-life after dilution in milk replacer according to instructions: 6 hours

Once opened, use by __/__

21. Marketing authorisation number

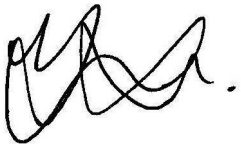
Vm 28365/4012

22. Manufacturer's batch number

Batch << >>

LEAFLET

(All information is included in the label/outer package)



Approved: 01 September 2022