ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pulmotil AC 250 mg/ml concentrate for oral solution for chickens, turkeys, pigs and cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
250.0 mg of Tilmicosin as phosphate salt.

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Propyl gallate	0.2 mg
Disodium edetate	2.0 mg
Phosphoric acid (for pH adjustment)	
Purified water	

Clear yellow to amber coloured solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens
Turkeys
Pigs
Cattle (pre-ruminant)

3.2 Indications for use for each target species

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

Chickens (except hens producing eggs for human consumption): 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.

Cattle (pre-ruminant): For the treatment and metaphylaxis of bovine respiratory disease, associated with *Mannheimia haemolytica, Pasteurella multocida, Mycoplasma bovis* and *M. dispar* susceptible to tilmicosin.

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

3.3 Contraindications

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

3.4 Special warnings

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 veterinary medicinal product.

Repeated use of the veterinary medicinal product should be avoided by improving management practices and thorough cleansing and disinfection.

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.

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 this 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
For oral use only. Contains disodium edetate. Do not inject.
Use of this veterinary medicinal product should be based on identification and susceptibility testing of the target pathogens. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies
An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

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 veterinary medicinal product. Wash hands after use.
In the case of accidental ingestion, wash out mouth immediately with water and seek medical advice and show the package insert or label to the physician. 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 veterinary medicinal product if you are allergic to ingredients in the veterinary medicinal 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.

Special precautions for the protection of the environment
The active substance tilmicosin is persistent in soils. Tilmicosin is known to be toxic to aquatic organisms. Manure from treated animals should not be deposited on the same field in successive years.

3.6 Adverse events

Chickens, turkeys, pigs and cattle:

Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Decreased drinking

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

Laying birds:
Do not use in birds in lay and within 2 weeks before the start of the laying period.

3.8 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.

3.9 Administration routes and dosage

Oral use. The veterinary medicinal product must be diluted in drinking water (pigs, chickens, turkeys) or milk replacer (cattle) before administration.

Pigs: To be included in the drinking water to provide a daily dose of 15-20 mg tilmicosin/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 tilmicosin /kg bodyweight in chickens and 10-27 mg tilmicosin /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).

Cattle: To be included in milk replacer only, at a dose of 12.5 mg tilmicosin /kg bodyweight and given twice daily for 3-5 consecutive days, which may be achieved by the inclusion of 1 ml of veterinary medicinal 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 cattle 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 intake of medicated drinking water/milk replacer depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of tilmicosin may need to be adjusted accordingly.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

When pigs are offered drinking water containing 300 or 400 mg tilmicosin /litre (equivalent to 22.5-40 mg tilmicosin /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 tilmicosin /litre (equivalent to 75-100 mg tilmicosin /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 a softer faecal consistency.

No symptoms of overdose have been seen in turkeys given drinking water containing levels of tilmicosin up to 375 mg tilmicosin /litre (equivalent to 50-135 mg tilmicosin /kg bodyweight 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.

No symptoms of overdose, with exception of a slight decrease in the milk consumption, have been seen in cattle given twice daily doses 5 times the maximum recommended dose or for twice the maximum recommended duration of treatment.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

Cattle:
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 2 weeks before the start of the laying period.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01FA91.

4.2 Pharmacodynamics

Tilmicosin is a semi-synthetic antibiotic of the macrolide group and is believed to affect protein synthesis. It has bacteriostatic action but at high concentrations it may be bactericidal. This antibacterial activity is predominantly against Gram-positive microorganism with activity against certain gram-negative ones and Mycoplasma of a bovine, porcine, ovine and avian origin. In particular, its activity has been demonstrated against the following microorganism:

- Pigs: *Mycoplasma hyopneumoniae, Pasteurella multocida* and *Actinobacillus pleuropneumoniae*
- Chickens and turkeys: *Mycoplasma gallisepticum* and *Mycoplasma synoviae*
- Cattle: *Mannheimia haemolytica, Pasteurella multocida, Mycoplasma bovis* and *M. dispar.*

CLSI breakpoints	resistant	intermediate	susceptible
Bovine *Mannheimia haemolytica*	≥ 32 µg/ml	16 µg/ml	≤ 8 µg/ml
Porcine *Pasteurella multocida*	≥ 32 µg/ml		≤ 16 µg/ml
Porcine *Actinobacillus pleuropneumoniae*	≥ 32 µg/ml		≤ 16 µg/ml

Scientific evidence suggests that macrolides act synergistically with the host immune system. Macrolides appear to enhance phagocyte killing of bacteria. Tilmicosin has been shown to inhibit *in vitro* the replication of the Porcine Reproductive and Respiratory Syndrome virus in alveolar macrophages in a dose dependent fashion.

Cross-resistance between tilmicosin and other macrolides and lincomycin has been observed. Macrolides inhibit protein synthesis by reversibly binding to the 50S ribosomal subunit. Bacterial growth is inhibited by induction of separation of peptidyl transfer RNA from the ribosome during the elongation phase. Ribosomal methylase, encoded by the *erm* gene, can precipitate resistance to macrolides by alteration of the ribosomal binding site.
The gene that encodes for an efflux mechanism, *mef*, also brings about a moderate degree of resistance.
Resistance is also brought about by an efflux pump that actively rids the cells of the macrolide. This efflux pump is chromosomally mediated by genes referred to as *acrA* and *acrB* genes.

4.3 Pharmacokinetics

Whilst blood concentrations of tilmicosin are low, there is pH-dependent macrophage accumulation of tilmicosin in inflamed tissues.

Pigs: After oral administration of 200 mg tilmicosin/L drinking water, the average active substance concentrations detected in lung tissue, alveolar macrophages and bronchial epithelium 5 days after the start of treatment were 1.44 µg/ml, 3.8 µg/ml and 7.4 µg/g respectively.

Poultry: As early as 6 hours after oral administration of 75 mg tilmicosin/L drinking water, the average active substance concentrations detected in lung and alveolar tissue were 0.63 µg/g and 0.30 µg/g respectively. 48 hours after the start of treatment, the tilmicosin concentrations in lung and alveolar tissue were 2.3 µg/g and 3.29 µg/g respectively.

Cattle: As early as 6 hours after oral administration of 25 mg tilmicosin/kg body weight/day in milk replacer, an average active substance concentration of 3.1 µg/g was detected in lung tissue. 78 hours after the start of treatment, the tilmicosin concentration in lung tissue was 42.7 µg/g. Therapeutically effective concentrations of tilmicosin were measured up to 60 hours after treatment.

Turkeys: After oral administration of 75 mg tilmicosin/L drinking water, the average active substance concentrations detected in lung tissue, air sac tissue and plasma 5 days after the start of treatment were 1.89 µg/ml, 3.71 µg/ml and 0.02 µg/g respectively. The highest mean tilmicosin concentration detected for lung tissues was 2.19 µg/g at 6 days; for air sac tissue it was 4.18 µg/g at 2 days and in the plasma it was 0.172 µg/g at 3 days.

Environmental properties

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 3 months.
Shelf life after dilution in drinking water: 24 hours.
Shelf life after dilution in milk replacer: 6 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

A polyethylene naphthalate amber coloured bottle containing 240 ml or 960 ml 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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

The veterinary medicinal product should not enter watercourses, as this may be dangerous for fish and other aquatic organisms.

Manure from treated animals should not be deposited on the same field in successive years**.**

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER 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

2. STATEMENT OF ACTIVE SUBSTANCES

Tilmicosin (as phosphate salt) 250 mg/ml.

3. PACKAGE SIZE

240 ml
960 ml

4. TARGET SPECIES

Chickens
Pigs
Turkeys
Cattle (pre-ruminant)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Pigs: Meat and offal: 14 days
Chickens: Meat and offal: 12 days
Turkeys: Meat and offal: 19 days
Cattle: 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 2 weeks before onset of the laying.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 3 months.

Once diluted in drinking water, use within 24 hours.
Once diluted in milk replacer, use within 6 hours.

9. SPECIAL STORAGE PRECAUTIONS

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

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 OF THE MARKETING AUTHORISATION HOLDER

<Elanco logo>

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Pulmotil AC 250 mg/ml concentrate for oral solution for chickens, turkeys, pigs and cattle

2. Composition

Each ml contains:
Active substance:
250.0 mg of Tilmicosin as phosphate salt.

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Propyl gallate	0.2 mg
Disodium edetate	2.0 mg
Phosphoric acid (for pH adjustment)	
Purified water	

Clear yellow to amber coloured solution.

3. Target species

Chickens
Turkeys
Pigs
Cattle (pre-ruminant)

4. Indications for use

Pigs: For the treatment and metaphylaxis of respiratory disease, associated with *Mycoplasma hyopneumoniae, Pasteurella multocida* and *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.

Cattle (pre-ruminant): For the treatment and metaphylaxis of bovine respiratory disease, associated with *Mannheimia haemolytica, Pasteurella multocida, Mycoplasma bovis* and *M. dispar* susceptible to tilmicosin.

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

5. Contraindications

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

6. Special warnings

Special warnings:
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 veterinary medicinal 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.
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 for safe use in the target species:
For oral use only. Contains disodium edetate; do not inject.
Use of this veterinary medicinal product should be based on identification and susceptibility testing of the target pathogens. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies.
An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

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 veterinary medicinal product. Wash hands after use.
In the case of accidental ingestion, wash out mouth immediately with water and seek medical advice and show the package insert or label to the physician. 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 veterinary medicinal product if you are allergic to ingredients in the veterinary medicinal 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
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

Laying birds:
Do not use in birds in lay and within 2 weeks before the start of the laying period.

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:
When pigs are offered drinking water containing 300 or 400 mg tilmicosin /litre (equivalent to 22.5-40 mg tilmicosin /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 tilmicosin /litre (equivalent to 75-100 mg tilmicosin /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 tilmicosin /litre (equivalent to 50-135 mg tilmicosin /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 cattle given twice daily doses 5 times the maximum recommended dose or for twice the maximum recommended duration of treatment.

Major 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.

7. Adverse events

Chickens, turkeys, pigs and cattle:

Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Decreased drinking

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 or the local representative of 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, routes and method of administration

Oral use. The veterinary medicinal product must be diluted in drinking water (pigs, chickens, turkeys) or milk replacer (cattle) before administration.

Pigs: To be included in the drinking water to provide a daily dose of 15-20 mg tilmicosin /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 tilmicosin /kg bodyweight in chickens and 10-27 mg tilmicosin /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).

Cattle: To be included in milk replacer only, at a dose of 12.5 mg tilmicosin /kg bodyweight and given twice daily for 3-5 consecutive days, which may be achieved by the inclusion of 1 ml of veterinary medicinal 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 cattle 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 intake of medicated drinking water/milk replacer depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of tilmicosin may be adjusted accordingly.

9. Advice on correct administration

Not applicable.

10. Withdrawal periods

Pigs:
Meat and offal: 14 days
Chickens:
Meat and offal: 12 days
Turkeys: Meat and offal: 19 days
Cattle:
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 2 weeks before 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 precautions for disposal

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.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.
Manure from treated animals should not be deposited on the same field in successive years**.**

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Bottle with 240 ml or 960 ml concentrate with a graduated polypropylene cup.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Manufacturer responsible for batch release:
Elanco France, 26 Rue de la Chapelle, 68330 Huningue, France

Local representatives and contact details to report suspected adverse reactions:

17. Other Information