
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tilmovet 250 mg/ml Concentrate for Oral Solution for pigs, chickens, turkeys *and cattle* (calves) (BE, BG, CZ, EL, HU, IE, NL, PL, RO, UK)

Tilmovet 250 mg/ml Concentrado en Solución Oral (ES)

Tilmovet 250 mg/ml Concentrado Liquido per Uso Orale (IT)

Tilmovet 250 mg/ml Solution Buvable (FR)

Tilmovet 250 mg/ml Lösung (AT)

Tilmovet 250 mg/ml Solução Oral (PT)

Tilmovet Vet, oral opløsning (DK)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Tilmicosin: 250 mg

Excipients:

Qualitative composition of excipients and other constituents
Propyl gallate (E310)
Disodium edetate
Phosphoric acid concentrated
Purified water

Clear yellow to amber solution

3. CLINICAL INFORMATION**3.1 Target species**

Chickens (broilers and pullets), turkeys, pigs and cattle (calves).

3.2 Indications for use for each target species

Pigs: For the treatment and metaphylaxis of respiratory infections associated with *Mycoplasma hyopneumoniae*, *Pasteurella multocida* and *Actinobacillus pleuropneumoniae*. The presence of the disease in the herd must be established before the veterinary medicinal product is used.

Chickens:

For the treatment and metaphylaxis of respiratory infections in poultry flocks associated with *Mycoplasma gallisepticum* and *Mycoplasma synoviae*. The presence of the disease in the herd must be established before the veterinary medicinal product is used.

Turkeys: For the treatment and metaphylaxis of respiratory infections in turkey flocks associated with *Mycoplasma gallisepticum* and *Mycoplasma synoviae*. The presence of the disease in the herd must be established before the veterinary medicinal product is used.

Cattle (calves): For the treatment and metaphylaxis of respiratory infections associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Mycoplasma bovis* and *Mycoplasma dispar*. The presence of the disease in the herd must be established before the veterinary medicinal product is used.

3.3 Contraindications

Do not administer to ruminating animals with active rumen function.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not allow horses or other equines access to drinking water containing tilmicosin..

Horses fed with water containing tilmicosin may present signs of toxicity with lethargy, anorexia, reduction of feed consumption, loose stools, colic, distension of the abdomen and death.

3.4 Special warnings

Tilmicosin should not be administered by injection to pigs. The veterinary medicinal product contains disodium edetate. The uptake of medicated water can be altered as a consequence of illness. If the uptake is insufficient alternative treatment may be required.

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

Cross-resistance has been shown between tilmicosin and other macrolides (like tylosin, erythromycin) or lincomycin. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to other macrolides or lincosamides because its effectiveness may be reduced.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Do not use when there is resistance to tilmicosin or cross resistance to other macrolides (like tylosin, erythromycin) or lincomycin.

Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to tilmicosin and may decrease the effectiveness of treatment with tilmicosin related substances.

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). 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 veterinary medicinal 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:

People with known hypersensitivity to tilmicosin should avoid contact with the veterinary medicinal product. The veterinary medicinal product may cause irritation or sensitisation by skin contact.

Avoid skin and ocular contact. Personal protective equipment consisting of protective gloves and protective clothes should be worn when handling the veterinary medicinal product.

Do not eat, drink or smoke when handling this product.

In case of contact with skin or eyes, rinse abundantly with fresh water. If irritation persists and in case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician, or call a poison center (dangers linked to disturbances in cardiac conduction).

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable

3.6 Adverse events

Chickens (broilers and pullets), turkeys, pigs and cattle (calves):

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

3.8 Interaction with other medicinal products and other forms of interaction

Tilmicosin may lessen the antibacterial activity of β -lactam antibiotics

Do not use simultaneously with bacteriostatic antimicrobial agents.

3.9 Administration routes and dosage

For oral use only. The veterinary medicinal product must be diluted in drinking water or milk replacer before administration.

To ensure a correct dosage, body weight should be determined as accurately as possible. The intake of medicated water 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.

Pigs:

15-20 mg tilmicosin per kg body weight for 5 days, i.e. 6-8 ml of veterinary medicinal product for 100 kg body weight corresponding to 80 ml of veterinary medicinal product per 100 litres of drinking water for 5 days.

Chickens (broilers and pullets):

15-20 mg tilmicosin per kg body weight for 3 days, i.e. 6-8 ml of veterinary medicinal product for 100 kg body weight corresponding to 30 ml of veterinary medicinal product per 100 litres of drinking water for 3 days.

Turkeys:

10-27 mg tilmicosin per kg body weight for 3 days, i.e. 4-11 ml of veterinary medicinal product for 100 kg body weight corresponding to 30 ml of veterinary medicinal product per 100 litres of drinking water for 3 days.

Calves:

12.5 mg tilmicosin per kg body weight two times per day for 3-5 days, i.e. 1 ml of veterinary medicinal product for 20 kg body weight two times per day for 3-5 days.

One 960 ml bottle is sufficient to medicate 1200 liters of drinking water for pigs or 3200 liters of drinking water for broilers, turkeys and pullets.

One 960 ml bottle is sufficient to medicate drinking water or milk replacer for 48 – 80 calves (40 kg b.w.).

One 240 ml bottle is sufficient to medicate drinking water or milk replacer for 8 calves (60 kg b.w.).

Medicated drinking water should be prepared fresh every 24 hours using only clean water. Medicated milk replacer should be prepared fresh every 4 hours using only clean water.

If signs of disease do not significantly improve within 3-5 days, the diagnosis should be re-evaluated and treatment changed.

Do not administer to pigs in a wet feeding system.

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

Pigs drink less water when a dose of 300 to 400 mg/liter (1.5 to 2 times the recommended dose) is administered. Although this will result in less intake of tilmicosin, it might lead to dehydration of the animals. Replace with untreated water when needed.

No symptoms were seen in poultry treated at 375 mg/liter for 5 days. A dose of 75 mg/liter for 10 days resulted in less consistent faeces.

No symptoms of overdose were noticed in turkeys treated at 375 mg/liter of drinking water for 3 days. No symptoms were noticed at 75 mg/liter for 6 days.

Except for a slight decrease in milk intake, no symptoms of overdose were seen in calves treated at 5 times the recommended dose or for twice the recommended treatment period.

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

Meat and offal:

Pigs: 14 days

Cattle (calves): 42 days.

Chickens (broilers and pullets): 12 days

Turkeys: 19 days

Not for use in birds producing eggs for human consumption.

Do not use within 2 weeks before the start of the laying period.

Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01FA91

4.2 Pharmacodynamics

Tilmicosin is a mainly bactericidal semi-synthetic antibiotic of the macrolide group. It is believed to affect bacterial protein synthesis.

Tilmicosin has a wide spectrum of activity against Gram-positive organisms and is particularly active against *Pasteurella*, *Actinobacillus* (*Haemophilus*) and *Mycoplasma* organisms of bovine, porcine and avian origin. Tilmicosin has some activity against certain Gram-negative micro-organisms. Cross resistance between tilmicosin and other macrolide antibiotics has been observed. Macrolides inhibit protein synthesis by reversibly binding to the 50S ribosomal subunit. Bacterial growth is inhibited by induction of the 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 *acrAB* genes. Resistance of *Pseudomonas* species and other Gram-negative bacteria, enterococci and staphylococci may be precipitated by chromosomally controlled alteration of permeability or uptake of the drug.

4.3 Pharmacokinetics

When administered orally to chickens, turkeys and pigs with drinking water and to calves with milk replacer, tilmicosin is absorbed and moves rapidly out of the serum into areas of low pH. This results in very low serum concentrations, but detectable levels of tilmicosin are found in lung tissue as early as 6 hours after starting the treatment. In chicken or turkeys, tilmicosin is also detected in pooled air sac tissue as early as 6 hours after starting the treatment. It is also known that tilmicosin is concentrated in alveolar macrophages of swine. When administered orally to calves tilmicosin is detected in lungs after 6 hours and remains at the therapeutic level up to 60 hours from the last dose.

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: 2 years

Shelf life after first opening the immediate packaging: 3 months

Shelf life after dilution in drinking water: 24 hours

Shelf life after reconstitution in milk replacer: 4 hours

5.3 Special precautions for storage

As packaged for sale: Do not store above 30°C. Protect from frost. Protect from light.

After dilution in drinking water / milk replacer: Protect from light.

5.4 Nature and composition of immediate packaging

960 ml is presented in a white high density polyethylene bottle with white polypropylene or high density polyethylene, tamper-evident cap; 240 ml is presented in high density polyethylene (HDPE) bottle with a tamper-evident screw closure made of polypropylene (PP).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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 system applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

To be completed nationally.

Date of first authorisation: <{DD/MM/YYYY}><{DD month YYYY}>.

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

To be completed nationally.

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month 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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

A. Labelling**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (ABSENCE OF OUTER PACKAGE)**

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tilmovet 250 mg/ml Concentrate for Oral Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Tilmicosin: 250 mg

3. PACKAGE SIZE

960 ml

240 ml

4. TARGET SPECIES

Chickens (broilers and pullets), turkeys, pigs and cattle (calves).

5. INDICATIONS**6. ROUTES OF ADMINISTRATION**

For oral use only. For use in drinking water or milk replacer

7. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: Pigs: 14 days

Cattle (calves): 42 days.

Chickens (broilers and pullets): 12 days

Turkeys: 19 days

Not for use in birds producing eggs for human consumption.

Do not use within 2 weeks before the start of the laying period.

Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp {mm/yyyy}

Shelf life after first opening the immediate packaging: 3 months

Shelf life after dilution in drinking water: 24 hours

Shelf life after reconstitution in milk replacer: 4 hours

Once opened use by:

9. SPECIAL STORAGE PRECAUTIONS

As packaged for sale: Store below 30°C. Protect from frost. Protect from light.
After dilution in drinking water / milk replacer: Protect from light.

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

Huvepharma NV

14. MARKETING AUTHORISATION NUMBER(S)**15. BATCH NUMBER**

Lot {number}

B. PACKAGE LEAFLET**1. Name of the veterinary medicinal product**

Tilmovet 250 mg/ml Concentrate for Oral Solution for pigs, chickens, turkeys and cattle (calves).

2. Composition

Each ml contains:

Tilmicosin: 250 mg

Clear yellow to amber solution

3. Target species

Chickens (broilers and pullets), turkeys, pigs and cattle (calves).

4. Indications for use

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

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

Chickens:

For the treatment and metaphylaxis of respiratory infections in poultry flocks associated with *Mycoplasma gallisepticum* and *Mycoplasma synoviae*.

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

Turkeys: For the treatment and metaphylaxis of respiratory infections in turkey flocks associated with *Mycoplasma gallisepticum* and *Mycoplasma synoviae*.

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

Cattle (calves): For the treatment and metaphylaxis of respiratory infections associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Mycoplasma bovis* and *Mycoplasma dispar*.

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

5. Contraindications

Do not administer to ruminating animals with active rumen function.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not allow horses or other equines access to drinking water containing tilmicosin.

Horses fed with water containing tilmicosin may present signs of toxicity with lethargy, anorexia, reduction of feed consumption, loose stools, colic, distension of the abdomen and death.

6. Special warnings

Special warnings:

Tilmicosin should not be administered by injection to pigs. The veterinary medicinal product contains disodium edetate. The uptake of medicated water can be altered as a consequence of illness. If the uptake is insufficient alternative treatment may be required.

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

Cross-resistance has been shown between tilmicosin and other macrolides (like tylosin, erythromycin) or lincomycin. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to other macrolides or lincosamides because its effectiveness may be reduced.

The sensibility of bacteria for tilmicosin may have changed over time or geographically.

Special precautions for safe use in the target species:

Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to tilmicosin and may decrease the effectiveness of treatment with tilmicosin related substances.

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). 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 veterinary medicinal 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:

People with known hypersensitivity to tilmicosin should avoid contact with the veterinary medicinal product. The veterinary medicinal product may cause irritation or sensitisation by skin contact, Avoid skin and ocular contact.

Personal protective equipment consisting of protective gloves and protective clothes should be worn when handling the veterinary medicinal product.

Do not eat, drink or smoke when handling this product.

In case of contact with skin or eyes, rinse abundantly with fresh water. If irritation persists and in case of accidental ingestion, seek medical advice immediately or call a poison center (dangers linked to disturbances in cardiac conduction).

Wash hands after use.

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

Interaction with other medicinal products and other forms of interaction:

Tilmicosin may lessen the antibacterial activity of β -lactam antibiotics

Do not use simultaneously with bacteriostatic antimicrobial agents.

Overdose:

Pigs drink less water when a dose of 300 to 400 mg/liter (1.5 to 2 times the recommended dose) is administered. Although this will result in less intake of tilmicosin, it might lead to dehydration of the animals. Replace with untreated water when needed.

No symptoms were seen in poultry treated at 375 mg/liter for 5 days. A dose of 75 mg/liter for 10 days resulted in less consistent faeces.

No symptoms of overdose were noticed in turkeys treated at 375 mg/liter of drinking water for 3 days. No symptoms were noticed at 75 mg/liter for 6 days.

Except for a slight decrease in milk intake, no symptoms of overdose were seen in calves treated at 5 times the recommended dose or for twice the recommended treatment period.

Major incompatibilities:

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

7. Adverse events

Chickens (broilers and pullets), turkeys, pigs and cattle (calves):

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

For oral administration following dilution in drinking water or milk replacer.

Pigs:

15-20 mg tilmicosin per kg body weight for 5 days, i.e. 6-8 ml of veterinary medicinal product for 100 kg body weight corresponding to 80 ml of veterinary medicinal product per 100 litres of drinking water for 5 days.

Chickens (broilers and pullets):

15-20 mg tilmicosin per kg body weight for 3 days, i.e. 6-8 ml of veterinary medicinal product for 100kg body weight corresponding to 30 ml of veterinary medicinal product per 100 litres of drinking water for 3 days.

Turkeys:

10-27 mg tilmicosin per kg body weight for 3 days, i.e. 4-11 ml of veterinary medicinal product for 100kg body weight corresponding to 30 ml of veterinary medicinal product per 100 litres of drinking water for 3 days.

Calves:

12.5 mg tilmicosin per kg body weight two times per day for 3-5 days, i.e. 1 ml of veterinary medicinal product for 20 kg body weight two times per day for 3-5 days.

If signs of disease do not significantly improve within 3-5 days, the diagnosis should be re-evaluated and treatment changed.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible. The intake of medicated water 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.

One 960 ml bottle is sufficient to medicate 1200 liters of drinking water for pigs or 3200 liters of drinking water for broilers, turkeys and pullets.

One 960 ml bottle is sufficient to medicate drinking water or milk replacer for 48 – 80 calves (40 kg b.w.).

One 240 ml bottle is sufficient to medicate drinking water or milk replacer for 8 calves (60 kg b.w.).

Medicated drinking water should be prepared fresh every 24 hours using only clean water.

Medicated milk replacer should be prepared fresh every 4 hours using only clean water

Do not administer to pigs in a wet feeding system.

10. Withdrawal periods

Meat and offal: Pigs: 14 days
 Cattle (calves): 42 days.
 Chickens (broilers and pullets): 12 days
 Turkeys: 19 days

Not for use in birds producing eggs for human consumption.

Do not use within 2 weeks before the start of the laying period.

Not authorised for use in animals producing milk for human consumption.

11. Special storage precautions

Keep out of the reach and sight of children.

Store below 30°C. Protect from frost. Protect from light.

Shelf life after first opening the immediate packaging: 3 months

Shelf life after dilution in drinking water according to directions: 24 hours

Shelf life after reconstitution in milk replacer according to directions: 4 hours

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.

12. Special precautions for disposal

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 applicable national collection system. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

240 ml and 960 ml bottle

Not all pack sizes may be marketed

15. Date on which the package leaflet was last revised

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:

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium
+32 3 288 18 49
pharmacovigilance@huvepharma.com

Manufacturer responsible for batch release:

Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

Local representatives and contact details to report suspected adverse reactions:

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

17. Other information

When the container is broached for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any veterinary medicinal product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.