SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tilmovet 100 mg/g granules for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains

Active substance:
Tilmicosin: 100 mg

Excipients:

Qualitative composition of excipients and other constituents
Corn cobs
Liquid paraffin
Macrogolglycerol ricinoleate
Phosphoric acid, concentrated for pH adjustment

A brown granulated powder.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (weaned piglets and pigs for fattening)

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for the treatment of pneumonia in pigs (weaned piglets) and pigs (for fattening), caused by *Actinobacillus pleuropneumoniae, Mycoplasma hyopneumoniae, Pasteurella multocida* sensitive to tilmicosin.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Tilmicosin is known to be toxic for horses. Do not allow horses or other equines access to feeds containing tilmicosin.
Horses fed with tilmicosin medicated feeds 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

If for an individual animal, feed intake is such that the recommended dosage is not reached, medication should be carried out by parenteral treatment.

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:

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.
Due to likely variability (time, geographical) in the occurrence of the resistance of bacteria for tilmicosin, bacteriological sampling and susceptibility testing are recommended.

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.

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

Accidental ingestion should be avoided by humans.
People with known hypersensitivity to tilmicosin or other macrolide antibiotics should avoid contact with the veterinary medicinal product.
May cause sensitisation by skin contact. May cause skin and eye irritation. Avoid direct skin contact. Personal protective equipment consisting of overalls, safety glasses and impervious gloves should be worn when handling the veterinary medicinal product. Wash affected parts if skin contact occurs. If accidental eye contact occurs, immediately rinse thoroughly with water. In case of accidental ingestion, or if you develop symptoms following exposure such as skin rash, seek medical advice immediately and show the package leaflet or the label to the physician.
Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.
If the operations involve the risk of exposure to dust, wear either a disposable filter and half mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 fitted with a filter to EN143. This warning is particularly relevant to on-farm mixing, where the risk of exposure to dust is likely to be enhanced.

Special precautions for the protection of the environment:

Not applicable.

Other precautions
Not applicable.

3.6 Adverse events

Pigs:

Undetermined frequency (cannot be estimated from available data)	Reduced food intake, food refusal[1]

[1] this effect is transient

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 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:
Laboratory studies in rats have not produced any evidence of a teratogenic, foetotoxic/embryotoxic effect of tilmicosin, however, a maternotoxicity was observed at doses that were close to the therapeutic dosage. The veterinary medicinal product can be used in sows whatever the pregnancy stages

Fertility:
The safety of the veterinary medicinal product has not been established in boars used for breeding purposes.

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.
For oral administration after incorporation into feed.

The veterinary medicinal product should be administered to small quantities of feed for immediate consumption by individual animals. For treatment of groups of pigs, use an appropriate premix incorporated into medicated feedingstuff by an authorised feed manufacturer. Pigs to be treated should be separated and treated individually. The required quantity of the veterinary medicinal product should be thoroughly mixed into the daily ration for each individual pig. The feed containing the oral granules should be provided as the sole ration for the periods recommended.

Individual pigs should receive 16 mg tilmicosin per kg bodyweight, corresponding to 160 mg veterinary medicinal product/kg bodyweight, once a day for 15 days. To ensure a correct dosage, body weight should be determined as accurately as possible and the amount of feed that the pig is likely to consume should be estimated. The correct quantity of the veterinary medicinal product should be added to the estimated quantity of daily ration for each pig, in a bucket or similar receptacle, and thoroughly mixed. The veterinary medicinal product should only be added to dry non-pelleted feed.

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

Vomiting and cardio-vascular collapse are symptoms of overdosing.

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: 21 days.

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 the bacterial protein synthesis *in vitro* and *in vivo*, without affecting the nucleic acid synthesis. It is mostly bacteriostatic. It has a bactericidal effect on *Pasteurella* spp.
Tilmicosin has a wide spectrum of activity against Gram-positive organisms and is particularly active against (*Pasteurella*, *Actinobacillus pleuropneumoniae*) and *Mycoplasma* organisms of porcine 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 Gramnegative bacteria, enterococci and staphylococci may be precipitated by chromosomally controlled alteration of permeability or uptake of the drug.

4.3 Pharmacokinetics

Absorption: When administered to pigs via the oral route at a dose of 400 ppm in the feed (equivalent to approximately 21.3 mg/kg/day), tilmicosin moves rapidly out of the serum into areas of low pH. The highest concentration in the serum (0.23±0.08 µg/ml) was recorded on day 10 of medication, but concentrations above the limit of quantification (0.10 µg/ml) were not found in 3 out of 20 animals examined. Lung concentrations increased rapidly between days 2 and 4, but no significant changes were obtained following four days of dosing. The maximum concentration in lung tissue (2.59±1.01 µg/ml) was recorded on day 10 of medication.

Distribution: Following oral administration, tilmicosin is distributed throughout the body, but especially high levels are found in the lung and in lung tissue macrophages. It is also distributed in the liver and kidney tissues.

Biotransformation: Several metabolites are formed, the predominant one being identified as T1. However the bulk of the tilmicosin is excreted unchanged.

Elimination: Following oral administration, tilmicosin is excreted mainly via the bile into the faeces, but a small proportion is excreted via the urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix into feed containing bentonite.

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.
Feed to which the oral granules has been added should be replaced if not consumed within 24 hours.
Store in the original container in order to protect from moisture.

5.3 Special precautions for storage

Do not store above 30ºC. Store in the original container in order to protect from moisture.

5.4 Nature and composition of immediate packaging

Pack of 0.25 kg or 1 kg in a polyethylene-lined 3-ply paper bag
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.

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

7. MARKETING AUTHORISATION NUMBERS

Vm 30282/3024
Vm 30282/5022

8. DATE OF FIRST AUTHORISATION

14 October 2009

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

November 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved 27 February 2025