PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE
Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Tilmicosin: 250 mg per ml.

3. PHARMACEUTICAL FORM

Concentrate for oral solution

4. PACKAGE SIZE

960 ml
240 ml

5. TARGET SPECIES

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

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

To be administered orally following dilution in drinking water or milk replacer
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

Eggs: Not authorised for use in birds producing eggs for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Tilmicosin should not be administered by injection to pigs. The 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

10. EXPIRY DATE

<EXP {month/year}>
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:

11. SPECIAL STORAGE CONDITIONS

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

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

Any unused veterinary product or waste materials derived from such veterinary medicinal products should be disposed of 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

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Huvepharma N.V.
Uitbreidingstraat 80
2600 Antwerpen
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 30282/4001

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

B. PACKAGE LEAFLET

Tilmovet 250 mg/ml Concentrate for Oral Solution
for pigs, chickens, turkeys and calves

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

Marketing authorisation

Huvepharma N.V, Uitbreidingstraat 80, 2600 Antwerpen, Belgium

Manufacturer responsible for batch release

Biovet JSC, 39 Petar Rakov Str, 4550 Peshtera, Bulgaria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tilmovet 250 mg/ml Concentrate for Oral Solution

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

Tilmicosin: 250 mg per ml

4. INDICATION(S)

Pigs: For the treatment and prevention of respiratory infections associated with *Mycoplasma hyopneumoniae*, *Pasteurella multocida and Actinobacillus pleuropneumoniae* when the disease has been diagnosed at the herd level.

Chickens:
For the treatment and prevention of respiratory infections in poultry flocks associated with *Mycoplasma gallisepticum and Mycoplasma synoviae* when the disease has been diagnosed at the herd level.

Turkeys: For the treatment and prevention of respiratory infections in turkey flocks associated with *Mycoplasma gallisepticum* and *Mycoplasma synoviae* when the disease has been diagnosed at the herd level.

Calves: For the treatment and prevention of respiratory infections associated with *Mannheimia haemolytica*, *P. multocida, Mycoplasma bovis and M.dispar* when the disease has been diagnosed at the herd level.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance or in cases of known resistance to tilmicosin. Do not use in horses.

6. ADVERSE REACTIONS

None known.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 product for 100 kg body weight corresponding to 80 ml of product per 100 litres of drinking water for 5 days.
Chickens:
15-20 mg tilmicosin per kg body weight for 3 days, i.e. 6-8 ml of product for 100kg body weight corresponding to 30 ml of 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 product for 100kg body weight corresponding to 30 ml of 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 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.

To avoid underdosing body weight should be determined as accurately as possible. The uptake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of the product has to be adjusted accordingly

Do not administer to pigs in a wet feeding system.

9. ADVICE ON CORRECT ADMINISTRATION

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 during 5 days. A dose of 75 mg/liter during 10 days resulted in less consistent faeces.
The sensibility of bacteria for tilmicosin may have changed over time or geographically

10. WITHDRAWAL PERIOD

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

Eggs: Not authorised for use in birds producing eggs for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store below 30°C. Do not refrigerate. 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 after the expiry date stated on the label.

12. SPECIAL WARNING(S)

Tilmicosin should not be administered by injection to pigs. The 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

Inappropriate use of the product may increase the prevalence of bacteria resistant to tilmicosin and may decrease the effectiveness of treatment with tilmicosin related substances. Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies
Cross resistance between tilmicosin and other macrolide antibiotics and lincosamides has been observed.
Tilmicosin may lessen the antibacterial activity of β-lactam antibiotics
Do not use simultaneously with bacteriostatic antimicrobial agents.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

People with known hypersensitivity to tilmicosin should avoid contact with the product. The veterinary medicinal product may cause irritation or sensitisation by skin contact,
Avoid skin and ocular contact. Wear protective gloves and protective clothes when handling the veterinary medicinal product.
In case of contact with skin or eyes, rinse abundantly with fresh water. If irritation persists and in case of incidental ingestion, seek immediately medical advice or call a poison center (dangers linked to disturbances in cardiac conduction).
Wash hands after use.

The safety of the product has not been established during pregnancy and lactation.
Use only in accordance with risk/benefit assessment by the responsible veterinarian.
Do not allow horses or other equines access to drinking water containing tilmicosin.

No symptoms of overdose were noticed in turkeys treated at 375 mg/liter of drinking water during 3 days. No symptoms were noticed at 75 mg/liter during 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 during twice the recommended treatment period.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

240 ml and 960 ml bottle
Not all pack sizes may be marketed

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

Approved: 01 February 2018

D Austin