ANNEX I

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE VETERINARY MEDICINAL PRODUCTS, ANIMAL SPECIES, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State	Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Route of administration
Austria	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Pulmotil AC	Oral solution	Tilmicosin 250mg/ml	Chickens Turkeys Pigs Calves	Oral
Belgium	Eli Lilly Benelux N.V. Elanco Animal Health Rue del'Etuve 52-Bte 1Stoofstraat 52 1000 Brussel Belgium	Pulmotil AC	Oral solution	Tilmicosin 250mg/ml	Chickens Turkeys Pigs Calves	Oral
Cyprus	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil AC	Oral solution	Tilmicosin 250 mg/ml	Chickens Pigs	Oral
Czech Republic	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil AC sol. ad us. vet.	Oral solution	Tilmicosin 250 mg/ml	Chickens (broilers) Pigs Calves	Oral
Germany	Lilly Deutschland GmbH Teichweg 3 35396 Gießen Germany	Pulmotil AC	Oral solution	Tilmicosin 250 mg/ml	Cattle (calves) Pigs for fattening Chickens	Oral
Greece	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil AC	Oral solution	Tilmicosin 250mg/ml	Chickens Turkeys Pigs Calves	Oral

Spain	Elanco Valquímica, S.A. Avenida de la Industría, 30 28108 – Alcobendas Madrid Spain	PULMOTIL AC	Oral solution	Tilmicosin 250mg/ml	Pigs Poultry (except laying hens) Turkeys Cattle	Oral
France	Lilly France SA Département Elanco Santé Animale 13 Rue Pagès 92158 Suresnes Cedex France	PULMOTIL AC	Oral solution	Tilmicosin 250mg/ml	Pigs Calves Chickens Turkeys	Oral
Hungary	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil AC oral solution	Oral solution	Tilmicosin 250mg/ml	Cattle (calf) Pigs Chickens Turkeys	Oral
Ireland	Elanco Animal Health Eli Lilly and Company Ltd Priestley Road Basingstoke Hampshire RG24 9NL United Kingdom	Pulmotil AC	Oral Solution	Tilmicosin 250mg/ml	Chicken Turkeys Pigs	Oral
United Kingdom	Elanco Animal Health Eli Lilly and Company Ltd Priestley Road Basingstoke Hampshire RG24 9NL United Kingdom	Pulmotil AC	Oral solution	Tilmicosin 250mg/ml	Chickens Turkeys	Oral

Italy	Eli Lilly Italia Elanco Animal Health Via A. Gramsci, 731-733 50019 Sesto Fiorentino Florence Italia	Pulmotil AC	Oral Solution	Tilmicosin 250mg/ml	Chickens Turkeys Pigs Calves	Oral
Luxembourg	Eli Lilly Benelux N.V. Elanco Animal Health Rue del'Etuve 52-Bte 1Stoofstraat 52 1000 Brussel Belgium	Pulmotil AC	Oral Solution	Tilmicosin 250mg/ml	Chickens Turkeys Pigs Calves	Oral
The Netherlands	Eli Lilly Nederland B.V. Elanco Animal Health Grootslag 1-5 3991 RA Houten The Netherlands	Pulmotil AC	Oral solution	Tilmicosin 250mg/ml	Chicken Turkey Pig Calves	Oral
Portugal	Lilly Portugal - Produtos Farmacêuticos, Lda Rua Dr. António Loureiro Borges, 1-piso 1, Arquiparque, Miraflores 1495-016 Algés Portugal	Pulmotil AC	Oral Solution	Tilmicosin 250mg/ml	Chickens Turkeys Pigs Calves	Oral
Poland	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil AC	Oral solution	Tilmicosin 250mg/ml	Chickens Pigs Calves	Oral
Slovak Republic	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil AC	Oral solution	Tilmicosin 250mg/ml	Chickens Pigs Calves	Oral

Romania	Eli Lilly Regional Operation Ges.m.b.H. Elanco Animal Health Kölblgasse 8-10 1030 Vienna Austria	Pulmotil AC	Oral solution	Tilmicosin 250mg/ml	Pigs Broilers Calves	Oral

ANNEX II

SCIENTIFIC CONCLUSIONS AND GROUNDS FOR AMENDMENT OF THE SUMMARY OF PRODUCT CHARACTERISTICS AND LABELLING

OVERALL SUMMARY OF THE SCIENTIFIC EVALUATION OF PULMOTIL AC AND ASSOCIATED NAMES

1. Introduction

Pulmotil AC 250 mg/ml concentrate for oral solution is currently registered in 18 European Member States. Eight marketing Authorisations were approved via the Mutual Recognition Procedure using Italy as the Reference Member State. The other marketing authorisations were approved via national procedures.

The referral relates to the divergent national decisions taken by Member States, raised by Germany. The main section of disharmony of the existing SPCs (non exhaustive) are:

> 4.1 Target species/ 4.2 Indications for Use, Specifying the Target Species: In some Member States the product is indicated for turkeys and in others not.
>
> 4.11 Withdrawal period(s): Withdrawal periods granted for the product vary among the Member States for all target species

2. Discussion

The Marketing Authorisation Holders submitted at the request of CVMP:
- an exhaustive list of differences between the SPCs of the product authorized in the member states;
- a proposal for a harmonised product information (SPC, labelling and package leaflet), taking into account the latest guidance;
- the available relevant data substantiating such proposed harmonised product information.

Efficacy in pigs

The CVMP has assessed two early dose determination studies, two definitive dose determination studies and eleven clinical study reports in pigs.

CVMP accepts that a claim for efficacy at a dose of 15-20 mg/kg bodyweight for 5 days, which may be achieved by the inclusion of 200 mg tilmicosin per litre for treatment and prevention of respiratory disease in pig herds, associated with *Mycoplasma hyopneumoniae, Pasteurella multocida, Actinobacillus pleuropneumoniae* and other organisms susceptible to tilmicosin has been demonstrated.

Efficacy in chickens (except hens producing eggs for human consumption)

The CVMP has assessed five dose determination studies provided by the Marketing Authorisation Holders.

The CVMP accepts that a claim for efficacy at a dose of 15-20 mg/kg bodyweight for 3 days for the treatment and prevention of respiratory disease in chicken flocks, associated with *Mycoplasma gallisepticum* and *M. synoviae* has been demonstrated.

Efficacy in calves (non-ruminant)

The CVMP has assessed three dose determination studies provided by the Marketing Authorisation Holders.

The CVMP accepts that a claim for efficacy at a dose of 12.5 mg/kg bodyweight (twice a day) for 5 days for the treatment and prevention of bovine respiratory disease, associated with *Mannheimia haemolytica, Pasteurella multocida, Mycoplasma bovis, M. dispar* has been demonstrated.

Efficacy in turkeys

The CVMP has assessed a dose determination studies and four clinical study reports in turkeys

The CVMP accepts that a claim for efficacy at a dose of 10-27 mg/kg body weight for 3 days for the treatment and prevention of respiratory disease in turkey flocks, associated with *Mycoplasma gallisepticum* and *M. synoviae*, has been demonstrated.

Withdrawal periods

The CVMP accepts the Marketing Authorisation Holders' proposal to harmonise the withdrawal period for all species on the basis of the pivotal residue studies presented.

Pigs - 14 days
Chickens - 12 days
Turkeys – 19 days
Calves - 42 days
Not for use in lactating animals.

As no Maximum Residue Limit has been set for tilmicosin in eggs, the following statement should be included in the SPC: Not authorised for use in laying birds producing eggs for human consumption. Do not use within 14 days of onset of the laying.

Shelf life

Based on the data presented, the following self-life periods are considered acceptable:

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 or reconstitution according to directions: 24 hours

SPC harmonisation:

The CVMP can accept the indication and posology in all species as these are in accordance with those used in the experimental and field studies.

The CVMP recommends that further changes to the SPC proposed by the Marketing Authorisation Holders are made:

- Propyl galate and disodium edentate should be included in Quantitative and Quantitative composition;
- The Phamaceutical Form should be: Concentrate for Oral Solution for use in drinking water or milk replacer';
- Contraindications: include a new statement in relation to the hypersensitivity to tilmicosin;
- Modified the special precautions to be taken by the person administering the veterinary medicinal product to animals;
- The follow statements should be included: Not authorised for use in laying birds producing eggs for human consumption. Do not use 14 days of onset of the laying;
- The pharmacodynamic properties have been reworded;
- The self life of the veterinary medicinal product as packaged for sale should be 2 years;
- The description of the nature and composition of immediate packaging has been harmonized.

Having considered the grounds for referral and the response provided by the Marketing Authorisation Holders, the CVMP concludes that the benefit/risk balance of the product is positive for use in pigs, chicken (except hens producing eggs for human consumption), calves (non-ruminant) and turkeys

subject to the recommended changes of Summary of the Product Characteristics and product information.

GROUNDS FOR AMENDMENT OF THE SUMMARY OF PRODUCT CHARACTERISTICS AND LABELLING

Whereas

- Propyl galate and disodium edentate are relevant to be listed in the quantitative and quantitative composition;
- The phamaceutical form appears to be “concentrate for oral solution for use in drinking water or milk replacer”;
- Contraindications should include a statement in relation to the hypersensitivity to tilmicosin;
- The special precautions to be taken by the person administering the veterinary medicinal product to animals need modification;
- The follow statements should be included: Not authorised for use in laying birds producing eggs for human consumption. Do not use 14 days of onset of the laying.;
- The pharmacodynamic properties need rewording;
- The shelf life of the veterinary medicinal product as packaged for sale is 2 years,

the CVMP has recommended the amendment of the Marketing Authorisations for which the Summary of Product Characteristics is set out in Annex III Pulmotil AC and associated names.

ANNEX III

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Tilmicosin (as phosphate) 250 mg/ml
Excipients:
Propyl gallate
Disodium edetate.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for Oral Solution for use in drinking water or milk replacer
Clear yellow to amber coloured solution.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (except hens producing eggs for human consumption)
Turkeys
Pigs
Calves (non ruminant)

4.2 Indications for use, specifying the target species

Pigs: For the treatment and prevention of respiratory disease in pig herds, associated with *Mycoplasma hyopneumoniae, Pasteurella multocida, Actinobacillus pleuropneumoniae* and other organisms susceptible to tilmicosin.

Chickens: For the treatment and prevention of respiratory disease in chicken flocks, associated with *Mycoplasma gallisepticum* and *M. synoviae.*

Turkeys: For the treatment and prevention of respiratory disease in turkey flocks, associated with *Mycoplasma gallisepticum* and *M. synoviae.*

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

4.3 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

4.4 Special warnings for each target species

Important: Must be diluted before administration to animals.

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 Pulmotil AC has to be adapted in a way that the recommended dosage will be taken up by the animals or different medication should be considered.

4.5 Special precautions for use

Special precautions for use in animals

For oral use only. Contains disodium edetate; do not inject

Severely ill individuals tend to drink less and may need simultaneous treatment, preferably by parenteral medication.

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. The use of the product should be based on susceptibility tests.

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

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, 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.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, a decrease in water intake has been observed.

4.7 Use during pregnancy, lactation or lay

The safety of tilmicosin has not been established in animals used for breeding purposes.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Pigs: To be included in the drinking water to provide a daily dose of 15-20 mg/kg bodyweight for 5 days, which may be achieved by the inclusion of 200 mg tilmicosin per litre (80 ml Pulmotil AC 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/kg bodyweight in chickens and 10-27 mg/kg bodyweight in turkeys for 3 days, which may achieved by the inclusion of 75 mg tilmicosin per litre (30 ml Pulmotil AC per 100 litres).

Calves: To be included in milk replacer only, at a dose of 12.5 mg/kg bodyweight and given twice daily for 3-5 consecutive days, which may be achieved by the inclusion of 1 ml of product every 20 kg bodyweight.

One 240 ml bottle of Pulmotil AC 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 Pulmotil AC are sufficient to medicate in milk replacer respectively 12 to 20 and 48 to 80 veal calves each of 40 kg bodyweight depending on the duration of treatment.

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Pigs - 14 days
Chickens - 12 days
Turkeys – 19 days
Calves - 42 days

Not authorised for use in laying birds producing eggs for human consumption. Do not use within 14 days of onset of the laying

Not for use in lactating animals.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: antibacterials for systemic use, macrolides.
ATC vet code: QJ01FA91

5.1 Pharmacodynamic properties

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*
- *Calves: Mannheimia haemolytica, Pasteurella multocida, Mycoplasma bovis and M. dispar*.

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.

5.2 Pharmacokinetic particulars

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.

Calves: 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Disodium edetate
Propyl gallate
Phosphoric acid (for pH adjustment)
Purified water

6.2 Incompatibilities
None known.

6.3 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 or reconstitution according to directions: 24 hours

6.4. Special precautions for storage

Do not store above 30˚ C. Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

The primary container is a polyethylene naphthalate amber coloured bottle containing 240 ml or 960 ml of Pulmotil AC, 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with national requirements.
Veterinary medicinal product must not be disposed of via waste water or the drainage systems.
Manure from treated animals should not be deposited on the same field in successive years**.**

7. MARKETING AUTHORISATION HOLDER

{For national implementation}

8. MARKETING AUTHORISATION NUMBER(S)

{For national implementation}

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

{For national implementation}

10 DATE OF REVISION OF THE TEXT

{For national implementation}

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Polyethylene naphthalate amber coloured bottle with a polypropylene screw top and polyethylene/aluminium/polyethylene terephthalate seal.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance: Tilmicosin (as phosphate) 250 mg/ml.
Excipients: Propyl gallate**,** Disodium edetate.

3. PHARMACEUTICAL FORM

Concentrate for oral solution for use in drinking water or milk replacer.

4. PACKAGE SIZE

240 ml
960 ml

5. TARGET SPECIES

Chickens (except hens producing eggs for human consumption)
Pigs
Turkeys
Calves (non ruminant)

6. INDICATION(S)

Pigs: For the treatment and prevention of respiratory disease in pig herds, associated with *Mycoplasma hyopneumoniae, Pasteurella multocida, Actinobacillus pleuropneumoniae* and other organisms susceptible to tilmicosin.

Chickens: For the treatment and prevention of respiratory disease in chicken flocks, associated with *Mycoplasma gallisepticum* and *M. synoviae*.

Turkeys: For the treatment and prevention of respiratory disease in turkey flocks, associated with *Mycoplasma gallisepticum* and *M. synoviae.*

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet on reverse of the label before use.
For oral use in drinking water or milk replacer.

8. WITHDRAWAL PERIOD

Pigs: 14 days
Chickens: 12 days
Turkeys: 19 days
Calves: 42 days

Not authorised for use in laying birds producing eggs for human consumption. Do not use within 14 days of onset of the laying

Not for use in lactating animals.

9. SPECIAL WARNING(S), IF NECESSARY

Important: Must be diluted before administration to animals.
For oral use only. Do not inject
Do not allow horses and other equines access to drinking water containing tilmicosin.

People with known hypersensitivity to tilmicosin should avoid contact with the product.

When mixing the veterinary medicinal product direct contact with eyes, skin and mucous membranes should be avoided. Personal protective equipment should be worn.

In case of accidental ingestion seek medical advice immediately and show the label to the physician.

10. EXPIRY DATE

EXP
Once opened, use within 3 months
Once reconstituted, use within 24 hours

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.
Protect from direct sunlight.

12. 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 products should be disposed of in accordance with national requirements.
Veterinary medicinal product must not be disposed of via waste water or the drainage systems.
Manure from treated animals should not be deposited on the same field in successive years**.**

13. 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.

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

{For national implementation}

16. MARKETING AUTHORISATION NUMBER(S)

{For national implementation}

17. MANUFACTURER'S BATCH NUMBER

Lot