ANNEX I

NAME, PHARMACEUTICAL FORM, STRENGTH OF THE MEDICINAL PRODUCT, ANIMAL SPECIES, ROUTES OF ADMINISTRATION, AND MARKETING AUTHORISATION HOLDER / APPLICANT

Member State	Applicant or Marketing Authorisation Holder	Product invented name	Pharmaceutical form	Strength	Indication	Recommended dose Frequency and route of administration
The Netherlands	Eurovet Animal Health Handelsweg 25 P.O. Box 179 5530 AD Bladel The Netherlands	Methoxasol-T	Solution for oral administration	Trimethoprim 20 mg/ml Sulfamethoxazole 100 mg/ml N-Methyl-2-	Pigs: Bronchial infections caused by *Pasteurella multocida*. Intestinal infections caused by *Escherichia coli* and *Salmonella spp.* Urogenital infections caused by *Escherichia coli* Non-egg-laying chickens: Bronchial infections caused by *Escherichia coli*, *Salmonella spp.* and *Pasteurella spp.*	Oral, via the drinking water Pigs: 2.5-5 mg trimethoprim and 12.5-25 mg sulfamethoxasole per kg body weight per day for 3-5 days Chickens: 5-12 mg trimethoprim and 25-58 mg sulfamethoxasole per kg body weight per day for 3-5 days
Germany	Eurovet Animal Health Handelsweg 25 P.O. Box 179 5530 AD Bladel The Netherlands	Methoxasol-T	As for The Netherlands	As for The Netherlands	Therapeutic treatment of infections caused by trimethoprim and sulfamethoxasole susceptible bacteria Pigs: *Pasteurella multocida, Actinobacillus pleuropneumoniae, Staphylococcus hyicus, E. coli, Haemophilus spp, Pasteurella haemolytica, salmonella cholerasuis, Salmonella thyphimurium, Streptococcus spp., Staphylococcus aureus, Staphylococcus spp*. Broilers: *Staphylococcus aureus, Salmonella enteritidis, E. coli*.	Oral, via the drinking water Methoxasol-T should be administered daily in drinking water over a period of 3-4 days: Pigs:20.8 mg sulfamethoxasole + 4.2 mg trimethoprim per kg body weight per day for 3-4 days. Broilers:27.5 mg sulfamethoxasole + 5.5 mg trimethoprim per kg body weight per day for 3-4 days.

Member State	Applicant or Marketing Authorisation Holder	Product invented name	Pharmaceutical form	Strength	Indication	Recommended dose Frequency and route of administration
Austria	Eurovet Animal Health Handelsweg 25 P.O. Box 179 5530 AD Bladel The Netherlands	Methoxasol – Lösung für Schweine und Hühner	As for The Netherlands	As for The Netherlands	For the treatment of respiratory tract infections, urogenital, gastrointestinal and skin infections caused by pathogens sensitive to trimethoprim and sulfamethoxasole in pigs and poultry (broilers).	As for Germany
Poland	Eurovet Animal Health Handelsweg 25 P.O. Box 179 5530 AD Bladel The Netherlands	Methoxasol	As for The Netherlands	As for The Netherlands	For treatment of infections caused by organisms sensitive to combination of trimethoprim and sulfamethoxasole. Pigs: Infections of the respiratory tract caused by *Pasteurella multocida*, *Actinobacillus pleuropneumoniae.* Infections of the digestive system caused by *Escherichia coli*, *Salmonella spp.* Infections of the urinary system caused by *Escherichia coli.* Hens: Infections of the respiratory tract caused by *Escherichia coli*, *Salmonella spp.*, *Pasteurella multocida.* Infections of the digestive system caused by *Salmonella spp.* *Polyarthritis* caused by susceptible *Escherichia coli*.	Oral, via the drinking water Pigs: 24 mg/kg b.w., equivalent to 1 litre of the drug in 500 L drinking water, for 3-4 days Hens: 33 mg/kg b.w., equivalent to 1 litre of the drug in 750 L drinking water, for 3-4 days

Member State	Applicant or Marketing Authorisation Holder	Product invented name	Pharmaceutical form	Strength	Indication	Recommended dose Frequency and route of administration
Hungary and Lithuania	Eurovet Animal Health Handelsweg 25 P.O. Box 179 5530 AD Bladel The Netherlands	Methoxasol	As for The Netherlands	As for The Netherlands	For the treatment of pigs and non-egg-laying chickens suffering from infectious diseases of the respiratory system caused by bacteria sensitive to sulfa-Methoxasole and trimethoprim, (e.g. porcine *A. pleuropneumoniae* and gallinaceous *E. coli*) and for prophylactic use.	Oral, via the drinking water Pigs: 24 mg of active ingredient compound per kilogram of body weight or 200 ml of the medicine per 1,000 kg of body weight per day. Poultry: 33 mg of active ingredient compound per kilogram of body weight or 275 ml of the medicine per 1,000 kg of body weight per day.

ANNEX II

SCIENTIFIC CONCLUSIONS

SCIENTIFIC CONCLUSIONS

1. Introduction and background

Methoxasol-T was authorised through a national procedure in the Netherlands in 1999 but a marketing authorisation was refused in Germany in 2001. Germany considered that the efficacy of Methoxasol-T as proposed by the applicant was not adequately justified, therefore resulting in a potential serious risk for the target animals. As to where Methoxasol-T is also authorised in Austria, Poland, Hungary, and Lithuania, these marketing authorisations have been included in the scope of the procedure. No member states, other than Germany, have reported the refusal of a marketing authorisation.

2. Discussion

1.1. Questions put to the Marketing Authorisation Holder

1. To provide the dossier submitted upon application for a marketing authorisation, for each Member State mentioned above (including Germany) and, if applicable, for any other Member State or country of the European Economic Area (EEA):
   a. Part I Summary of the dossier, including the Summary of Product Characteristics, the expert reports and the quantitative and qualitative composition of the product;
   b. Part IV Preclinical and clinical information.
   As many documents as possible, and at least the SPCs, should be presented in English.
2. To provide information on any addition, deletion or change made to the information as requested under point 1, after the initial application.
3. To detail differences that exist between the dossiers with respect to the information as requested under point 1 and 2.
4. To justify compliance of the dossier, as it exists in each Member State or EEA country, with respect to the requirements of Annex I of Directive 2001/82/EC, as amended.
5. To consider in particular the issues to which reference is made in the Annex to the referral notification from Germany as to the grounds for refusing an authorisation.
6. To justify with field data, the use of the product and the adequacy of the recommended dose for each of the claimed indications in pigs, except for the treatment and prevention of swine respiratory disease associated with *A. pleuropneumoniae* sensitive to trimethoprim and sulphamethoxazole.
7. To justify with field data, the use of the product and the adequacy of the recommended dose for each of the claimed indications in poultry. Comment is required on the current use of the product in poultry and in particular on the dose used or prescribed by veterinary surgeons under field conditions.
8. To propose and justify with data a suitable shelf life for the product, including an in-use shelf life where relevant.
9. To propose and justify a harmonised SPC text, including posology and method of administration as well as withdrawal periods for pigs and poultry.

1.2. Differences between dossiers

The dossier submitted to the Netherlands was only bibliographic. The dossier sent to Germany including the answers to the list of questions and to Poland, Hungary and Lithuania was almost the same, but with additional experimental clinical studies. Austria received a dossier similar to the original sent to Germany.

It can be concluded that the dossiers on which the Member States took their decisions were largely similar but not identical. The physical product manufactured for sale in the various markets appears to be identical.

1.3. Efficacy in pigs

The CVMP has assessed a pilot study, a main experimental study, 2 field trial reports as well as other efficacy, pharmacokinetics and tolerance data submitted by the marketing authorisation holder.

The CVMP accepts that a claim for efficacy at a dose of 25mg/kg for 4 days for the treatment of respiratory infections in pigs has been demonstrated.

The CVMP agrees that as long as the treatment is directed against respiratory infections in pigs, it is not necessary to perform additional field studies to demonstrate efficacy against other organisms with similar MIC levels as *A. pleuropleumonia*. However, for the use of the product confirmation of the presence of a specific infection and confirmation of a bacteriological cure is required.

As to where the SPC´s in The Netherlands, Austria and Poland, Methoxasol-T include indications that cover urogenital, gastrointestinal and skin infections, CVMP concludes that no data have been provided supporting these claims.

On the basis of further additional MIC data from various publications (including two 2004 published papers showing susceptibility of various isolates from pig respiratory samples from Denmark) and from resistance monitoring by the BVL in Germany in 2006, the CVMP can accept the proposed revision of the indication:

Pigs: Treatment and prevention of respiratory infections caused by *Actinobacillus pleuropneumoniae* susceptible to trimethoprim and sulfamethoxazole where the disease has been diagnosed in the herd. Resistance against potentiated sulphonamides may vary. Therefore the use of the product should be based on culture and sensitivity of micro-organisms from diseased cases on farm or from recent previous experience on the farm.

1.4. Efficacy in broilers

The CVMP has assessed an experimental study on clinical efficacy of Methoxasol-T for treatment of a respiratory infection caused by *E.coli* in chickens, as well as bibliographic and pharmacovigilance data provided by the marketing authorisation holder.

In respect of the benefit/risk balance for target species poultry, the CVMP concludes that:

- notwithstanding the fact that a definitive clinical field study using the recommended dosage of the product has not been provided, taking into account the pre-clinical studies, the artificial infection model, the history of use and the other pertinent information provided, the various risk management steps now set out in the proposed SPC and noting the fact that the indications for use are restricted, the benefit / risk balance is positive;
- the availability of an authorised veterinary medicinal product containing active substances other than fluoroquinolones might be regarded an indirect benefit and not directly relevant to the scope of this referral procedure (as efficacy must be shown for each product independently);
- the conditions of use as proposed in the SPC preclude use in laying birds and restrict use of the product based on culture and sensitivity testing of micro-organisms from diseased farms.

The CVMP can accept the proposed revision of the indication:
Broilers: Treatment and prevention of respiratory infections caused by *Escherichia coli* susceptible to trimethoprim and sulfamethoxazole where the disease has been diagnosed in the flock.
Resistance against potentiated sulphonamides may vary. Therefore the use of the product should be based on culture and sensitivity of micro-organisms from diseased cases on farm or from recent previous experience on the farm.

1.5. Shelf life

The Marketing Authorisation Holder presented 3 studies on shelf life and in-use shelf life. Based on these studies a 36 months shelf life for Methoxasol-T is claimed. Since no freezing studies have been performed the SPC must contain the note: Do not freeze.

The results of the in-use stability testing of the product after 15 months storage at 25°C/60% RH and in-use of 12 months after opening showed acceptable stability.

Finally a 24 hours in-use shelf-life is demonstrated for concentrated and therapeutic solutions of the product Methoxasol-T.

1.6. SPC harmonisation

The Marketing Authorisation Holder has proposed a new harmonised SPC.

Where the indications in both pigs and broilers are restricted to respiratory infections, the CVMP can accept this claim.

The CVMP can also accept the dose as these are in accordance with those used in the experimental and field studies.

The withdrawal period for Methoxasol-T varied between EU countries, pigs 3-5 days and non-laying hens 6-10 days. The MAH proposed a withdrawal period of 5 days in pigs and 6 days in broilers. Based on a residue study in pigs a 3 days withdrawal period was recommended. No statistical approach was followed because both TMP and SMX concentrations in muscle, liver, kidney and fat + skin were below limit of quantification at the first sampling point 2 days after cessation of Methoxasol- T medication. Thus it appears that 5 days is acceptable for pigs.

In an old study in broilers with a dose of 38.5mg /kg bwt depletion in skin and plasma demonstrated that the residues were below the MRL by 4 days. A residue depletion study in broilers was conducted following use of Methoxasol-T at a dose of 70mg/kg/day for 5 days. The residues were rapidly depleted. The data show that skin was a marker tissue and sulfamethoxazole the marker residue. Within 2 days following treatment residue concentrations of trimethoprim and sulphamethoxazole were below the MRL in all edible tissues, with the exception of skin. A GLP study on pharmacokinetics following water medication of 35 mg TMP/SMX per kg per day was carried out. Plasma elimination of both TMP and suphamethoxazole in broilers is more rapid than in pigs (TMP t½: <1 h in broilers vs 2.5 h in pigs; SMX t½: 1.7 h in broilers vs 2.3 h in pigs). Since there is no high tissue accumulation for any of the compounds it is expected that the depletion in broiler tissues is as rapid as the depletion in pigs. Consequently, the proposed withdrawal of 6 days in broilers is on the safe side.

The CVMP recommends the following changes to the SPC proposed by the MAH:

4.3 Contraindications
This section is strictly meant for contraindications relating to the safety of the treated animals. SPC guideline states: "Situations, which arise from a set of circumstances where the veterinary medicinal products must not be used for target animal safety reasons, i.e. absolute contraindications, are the subject of this section." The contraindication for laying birds should be deleted.

4.11 Withdrawal period
The sentence "Not permitted for use in laying birds..." should be changed to "Not authorised for use in laying birds..." in accordance with the SPC guideline.

5.1: Delete MIC data

5.2: protein binding for TMP and SMX is not high (TMP 50, SMX 60), but the overall proposal of the MAH can be accepted.

3. Conclusion

Having considered the grounds for referral and the responses provided by the Marketing Authorisation Holder, CVMP concludes that the benefit/risk balance of the product is positive for use in both pigs and broilers subject to the recommended changes to Summary of the Product Characteristics and product information.

ANNEX III

SUMMARY OF PRODUCT CHARACTERISTICS AND IMMEDIATE PACKAGING

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Methoxasol-T oral solution for pigs and broilers

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Per ml solution	Trimethoprim	20.0 mg
	Sulfamethoxazole	100.0 mg

Excipients:

N-methyl-pyrrolidone

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for oral administration.
Clear and yellow

4. CLINICAL PARTICULARS

4.1 Target species

Pigs and broilers.

4.2 Indications for use, specifying the target species

Pigs: Treatment and prevention of respiratory infections caused by *Actinobacillus pleuropneumoniae* susceptible to trimethoprim and sulfamethoxazole where the disease has been diagnosed in the herd.

Broilers: Treatment and prevention of respiratory infections caused by *Escherichia coli* susceptible to trimethoprim and sulfamethoxazole where the disease has been diagnosed in the flock.
Resistance against potentiated sulphonamides may vary. Therefore the use of the product should be based on culture and sensitivity of micro-organisms from diseased cases on farm or from recent previous experience on the farm.

4.3 Contraindications

Do not use in animals suffering from severe liver or kidney disease, oliguria or anuria.
Do not use in animals with impaired haematopoietic systems.

4.4 Special warnings for each target species

In broilers water intake should be checked regularly.
Severely diseased animals can have a decreased appetite and water consumption. If necessary the concentration of the VMP in the drinking water should be adjusted to make sure that the recommended dosage is being consumed. However if the concentration of the product is increased too much, the intake of the medicated drinking water decreases for palatability reasons. Therefore water intake should be monitored, especially in broilers.

4.5 Special precautions for use

Special precautions for use in animals
Due to the likely variability (time, geographical) in the occurrence of resistance of bacteria for trimethoprim/sulfamethoxazole bacteriological sampling and susceptibility testing are recommended.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
During preparation and administration of the medicated drinking water, skin contact with the drug should be avoided. Therefore it is recommended to wear impermeable gloves e.g. rubber or latex when applying the product. In case of allergy to trimethoprim or sulfonamides, special care should be taken when handling this product or the medicated solution. In the event of eye contact, rinse the eye with copious amounts of clean water and if irritation occurs, seek medical attention. In the event of accidental ingestion, seek medical advice. Wash hands and contaminated skin immediately after handling the product.

4.6 Adverse reactions (frequency and seriousness)

A diminished water intake in chickens may occur occasionally.
Hypersensitivity reactions can occur rarely.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay.

4.8 Interaction with other medicinal products and other forms of interaction

Do not combine with other veterinary medicinal products.

4.9 Amounts to be administered and administration route

Methoxasol-T is intended for oral administration with drinking water:
Pigs: 25 mg/kg bodyweight, corresponding to approximately 1 litre of the drug in 500 L drinking water, for 3-4 days.
Broilers: 33 mg/kg bodyweight, corresponding to approximately 1 litre of the drug in 750 L drinking water, for 3-4 days.

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

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

A 2 ½ fold overdose is well tolerated by pigs.
In chicken an acute overdose will not occur because the birds will be reluctant to drink the strongly concentrated drinking water (too bitter taste if above 2 litres Methoxasol-T per 1000 litre drinking water). Chronic overdose in chicken will result in a strongly diminished water- and feed intake and retarded growth.

4.11 Withdrawal period(s)

Pigs: 5 days
Broilers: 6 days
Not authorised for use in laying birds producing eggs for human consumption

5. PHARMACOLOGICAL PROPERTIES

Trimethoprim is a diaminopyrimidine, a synthetic folic acid antagonist. Sulfamethoxazole is a broad-spectrum antimicrobial agent belonging to the sulfonamides.
ATC vet classification (of the combination): QJ01E W

5.1 Pharmacodynamic properties

In vitro trimethoprim is generally bacteriostatic and has a broad spectrum of activity against both gram-positive and gram-negative bacteria. A synergistic and bactericidal effect occurs when trimethoprim is combined with sulfamethoxazole, because trimethoprim and sulfamethoxazole inhibit sequential steps in the synthesis of tetrahydrofolic acid, an essential metabolic cofactor in bacterial synthesis of purine and, subsequently, DNA.

5.2 Pharmacokinetic particulars

Following oral administration both active ingredients are rapidly absorbed from the gut. The C_{max} of sulfamethoxazole in pigs is approximately 6.2 µg/g. The C_{max} of trimethoprim is 0.29 µg/g. The C_{max} of sulfamethoxazole in chickens is approximately 9.0 µg/g, whereas that of trimethoprim is 0.12 µg/g.
High trimethoprim concentrations are found in the kidneys, the liver and the lungs. With the exception of the kidneys, sulfamethoxazole concentrations in the tissues are significantly lower than in the plasma. Protein binding for TMP and SMX is not very high.
The drug is primarily excreted through the kidneys (both actively and passively), but elimination also occurs through the faeces. Elimination is relatively fast both in poultry and pigs. Plasma elimination half-life for trimethoprim in poultry is less than 1 hour and that of sulfamethoxazole, approximately 1.5 hours. In pigs, elimination half-life for both substances is approximately 2.5 hours. Within 48 hours after the last medication trimethoprim, sulfamethoxazole and their metabolites are undetectable in urine and faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol,
Sodium hydroxide,
Water, purified,
N-methyl-pyrrolidone

6.2 Incompatibilities

Solubility and stability of Methoxasol-T in drinking water are pH-dependent.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
After first opening the remaining shelf life is 12 months.
Shelf-life after dilution or reconstitution according to directions: 24 hours

6.4. Special precautions for storage

Do not freeze

6.5 Nature and composition of immediate packaging

HDPE bottle / can: volume 1000 ml / 5000 ml.
The 1000 ml bottle is closed with a tamper-proof LDPE screw-cap.
The 5000 ml can is closed with a tamper-proof HDPE screw-cap.

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 local requirements.

7. MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.
Handelsweg 25, P.O.Box 179, 5530 AD Bladel,
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

IMMEDIATE PACKAGING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Methoxasol, oral solution for pigs and broilers.
Trimethoprim and sulfamethoxazole.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substances:

Per ml solution	Trimethoprim	20.0 mg
	Sulfamethoxazole	100.0 mg

Excipients:
N-methyl-pyrrolidone

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

HDPE bottle / can: volume 1000 ml / 5000 ml.
The 1000 ml bottle is closed with a tamper-proof LDPE screw-cap.
The 5000 ml can is closed with a tamper-proof HDPE screw-cap.

Not all pack sizes may be marketed.

5. TARGET SPECIES

Pigs and broilers

6. INDICATION(S)

Pigs: Treatment and control of respiratory infections caused by *Actinobacillus pleuropneumoniae* susceptible to trimethoprim and sulfamethoxazole where the disease has been diagnosed in the herd.

Broilers: Treatment and control of respiratory infections caused by *Escherichia coli* susceptible to trimethoprim and sulfamethoxazole where the disease has been diagnosed in the flock.

Resistance against potentiated sulphonamides may vary. Therefore the use of the product should be based on culture and sensitivity of micro-organisms from diseased cases on farm or from recent previous experience on the farm.

7. METHOD AND ROUTE(S) OF ADMINISTRATION, POSOLOGY

Methoxasol is intended for oral administration with drinking water:
Pigs: 25 mg/kg bodyweight, corresponding to approximately 1 litre of the drug in 500 L drinking water, for 3-4 days.
Broilers: 33 mg/kg bodyweight, corresponding to approximately 1 litre of the drug in 750 L drinking water, for 3-4 days.

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

8. WITHDRAWAL PERIOD

Pigs: 5 days
Broilers: 6 days
Not authorised for use in laying birds producing eggs for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in animals suffering from severe liver or kidney disease, oliguria or anuria.
Do not use in animals with impaired haematopoietic systems.

Hypersensitivity reactions can occur rarely.
In broilers water intake should be checked regularly.
Severely diseased animals can have a decreased appetite and water consumption. If necessary the concentration of the VMP in the drinking water should be adjusted to make sure that the recommended dosage is being consumed. However if the concentration of the product is increased too much, the intake of the medicated drinking water decreases for palatability reasons. Therefore water intake should be monitored, especially in broilers.

Special precautions for use in animals
Due to the likely variability (time, geographical) in the occurrence of resistance of bacteria for trimethoprim / sulfamethoxazole bacteriological sampling and susceptibility testing are recommended.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
During preparation and administration of the medicated drinking water, skin contact with the drug should be avoided. Therefore it is recommended to wear impermeable gloves e.g. rubber or latex when applying the product. In case of allergy to trimethoprim or sulfonamides, special care should be taken when handling this product or the medicated solution. In the event of eye contact, rinse the eye with copious amounts of clean water and if irritation occurs, seek medical attention. In the event of accidental ingestion, seek medical advice. Wash hands and contaminated skin immediately after handling the product.

Use during pregnancy and lactation
The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

Interactions
Do not combine with other veterinary medicinal products.

Overdose
A 2 ½ fold overdose is well tolerated by pigs.

In chicken an acute overdose will not occur because the birds will be reluctant to drink the strongly concentrated drinking water (too bitter taste if above 2 litres Methoxasol per 1000 litre drinking water). Overdose in chicken will result in a strongly diminished water- and feed intake and retarded growth.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

Keep out of the reach and sight of children.
Do not freeze

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OF RESTRICTIONS REGARDING SUPPLY AND USE

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 AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Eurovet Animal Health B.V.
Handelsweg 25, P.O.Box 179, 5530 AD Bladel, The Netherlands

16. MARKETING AUTHORISATION NUMBER

17. MANUFACTURER'S BATCH NUMBER

Batch.