ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adjusol TMP SULFA Liquide 83.35 mg/ml + 16.65 mg/ml solution for use in drinking water/milk (FR)
Adjusol TMP SULFA 83.35 mg/ml + 16.65 mg/ml solution for use in drinking water/milk (GR)
Adjusol TMP SULFA liquido 83.35 mg/ml + 16.65 mg/ml solution for use in drinking water/milk (PT)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains:

Active substances:
Sulfadiazine 83.35 mg
Trimethoprim 16.65 mg

Excipients:

Qualitative composition of excipients and other constituents
Macrogol 200
Sodium hydroxide (for pH adjustment)
Purified water

Light yellow solution, slightly viscous.

3. CLINICAL INFORMATION

3.1. Target species

Pre-ruminant calves, pre-ruminant lambs, pigs, rabbits and chickens

3.2. Indications for use for each target species

Pre-ruminant calves and lambs
Treatment and metaphylaxis of respiratory infections caused by *Pasteurella multocida* or *Mannheimia haemolytica* and infections caused by *Escherichia coli* susceptible to trimethoprim and sulfadiazine.

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

Pigs
Treatment and metaphylaxis of respiratory infections caused by *Pasteurella multocida* or *Actinobacillus pleuropneumoniae*, and infections caused by *Streptococcus suis* or *Escherichia coli* susceptible to trimethoprim and sulfadiazine.

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

Rabbits
Treatment and metaphylaxis of respiratory infections caused by *Pasteurella multocida*, and collibacillosis caused by *Escherichia coli* susceptible to trimethoprim and sulfadiazine.

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

Chickens
Treatment and metaphylaxis of collibacillosis caused by *Escherichia coli* susceptible to trimethoprim and sulfadiazine.

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

3.3. Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use in animals suffering from severe liver or kidney disease, oliguria or anuria.

3.4. Special warnings

Severely diseased animals can have a decreased appetite and water consumption. If necessary the concentration of the veterinary medicinal product in the drinking water should be adjusted to make sure that the recommended dosage is being consumed.

Pigs, pre-ruminant calves, pre-ruminant lambs and rabbits: The uptake of medication by animals may be altered as a consequence of illness. In case of insufficient water uptake, animals should be treated parenterally instead using a suitable injectable veterinary medicinal product prescribed by the veterinarian.

3.5. Special precautions for use

Special precautions for safe use in the target species:

Due to the likely variability (time, geographical) in susceptibility of bacteria for potentiated sulfonamides, occurrence of resistance of bacteria may differ from country to country and even from farm to farm, and therefore bacteriological sampling and susceptibility testing are recommended. It is particularly of importance for *E. coli* infections where high percentages of resistance are observed (see section 4.2).

Use of the veterinary medicinal product should be based on susceptibility testing of bacteria isolated from the animal. If not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Use of the veterinary medicinal product deviating from the instructions given in the Summary of product characteristics (SPC) may increase the prevalence of bacteria resistant to sulfadiazine and trimethoprim and may also decrease the effectiveness of combinations of trimethoprim with other sulfonamides due to the potential for cross-resistance.

Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.

To avoid deterioration of the kidneys due to crystalluria during treatment, it should be ensured that the animal receives sufficient amount of drinking water.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

This veterinary medicinal product contains sulfadiazine, trimethoprim and macrogol, which can cause allergic reactions in some people. Hypersensitivity to sulfonamides may lead to cross reactions with other antibiotics. Allergic reactions to these substances may occasionally be serious.

People with known hypersensitivity (allergy) to sulfonamides, trimethoprim or macrogol should avoid contact with the veterinary medicinal product.

This veterinary medicinal product may cause skin or eye irritation. During the preparation and administration of medicated drinking water, skin and eyes contact has to be avoided. Personal protective equipment consisting of waterproof gloves and safety glasses should be worn when handling the veterinary medicinal product. In case of accidental contact with the eyes or skin, wash the affected area with plenty of water, and if skin rash occurs, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

This veterinary medicinal product may be harmful if ingested. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6. Adverse events

Pre-ruminant calves, pre-ruminant lambs, pigs, rabbits and chickens:

Very rare (<1 animal / 10, 000 animals treated, including isolated reports):	Decreased drinking[1]
Undetermined frequency (cannot be estimated from the available data):	Hypersensitivity reaction

[1] In chickens

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:

Laboratory studies in rats and rabbits have shown evidence of teratogenic and foetotoxic effects.

Do not use during pregnancy and lactation.

Laying birds:

Do not use in birds in lay.

3.8. Interaction with other medicinal products and other forms of interaction

Do not administer concomitantly with coccidiostats or veterinary medicinal products containing sulfonamides.

Do not associate with PABA (para-aminobenzoic acid).

Sulfonamides potentiate anticoagulants action.

3.9. Administration routes and dosage

Administration route:
For oral use in drinking water/milk replacer.

Amounts to be administered:
Pre-ruminant calves and lambs
12.5 mg of sulfadiazine and 2.5 mg of trimethoprim per kg body weight (corresponding to 1.5 mL of solution per 10 kg body weight), every 12 hours for 4 to 7 consecutive days, to be mixed with the milk replacer (when adding the water).

Pigs and rabbits
25 mg of sulfadiazine and 5 mg of trimethoprim per kg of live weight per day (corresponding to 3 mL of solution per 10 kg live weight per day in continuous), for 4 to 7 consecutive days, to be diluted in drinking water.

Chickens
25 mg of sulfadiazine and 5 mg of trimethoprim per kg of live weight per day (corresponding to 0.3 mL of solution per kg of live weight per day in continuous), for 4 to 7 consecutive days, to be diluted in drinking water.

Guidance for preparing product solutions:
To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing. The intake of medicated water depends on the physiological and clinical condition of the animals. In order to obtain the correct dosage, the concentration of sulfadiazine and trimethoprim may need to be adjusted accordingly.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{Dose (mg product per kg body weight per day)} \times \text{Mean body weight (kg) of animals to be treated}}{\text{Mean daily water consumption (litre) per animal per day}} = \text{___ mg product per litre of drinking water/milk}$$

The medicated drinking water should be the sole source of drinking water for the treatment duration. Any medicated drinking water which is not consumed within 24 hours should be discarded.

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

Sulfonamides overdose causes renal toxicity. In this case, the administration of the veterinary medicinal product has to be stopped.

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

3.12. Withdrawal periods

Calves:

Meat and offal: 12 days.

Lambs:
Meat and offal: 12 days.

Pigs:
Meat and offal: 12 days.

Rabbits:
Meat and offal: 12 days.

Chickens: Meat and offal: 12 days.
Eggs: Not for use in birds producing or intended to produce eggs for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01EW10

4.2 Pharmacodynamics

Trimethoprim and sulfadiazine have a broad spectrum of activity against gram-positive and gram-negative bacteria including *Streptococcus suis, Pasteurella multocida, Actinobacillus pleuropneumoniae, Mannheimia haemolytica* and *E. coli in vitro*. Sulfonamides block the conversion of para-aminobenzoic acid to dihydrofolic acid. Their effect is bacteriostatic.

Trimethoprim inhibits dihydrofolic acid reductase, which converts dihydrofolic into tetrahydrofolic acid.

The effect of trimethoprim in combination with sulfonamides is bactericidal. Sulfonamides and trimethoprim thus cause a successive blockage of two enzymes that play an important role in the metabolism of bacteria. Their effect is synergistic and time dependent.

Bacterial resistance to trimethoprim and to sulfonamides can be mediated via 5 main mechanisms: (1) changes in the permeability barrier and/or efflux pumps, (2) naturally insensitive target enzymes, (3) changes in the target enzymes, (4) mutational or recombinational changes in the target enzymes, and (5) acquired resistance by drug-resistant target enzymes.

A summary of available susceptibility data of *E. coli* from the Vetpath IV (years 2015 and 2016) and from the 2019 Resapath program report is presented below.

Susceptibility data presented showed high levels of resistance among *E. coli* isolated from pigs (39% classified as susceptible in the VetPath IV data - n=333 - and 51% in Resapath data - n= 1834).

For calves, the VetPath IV data (n=230) showed a susceptibility of 70%, while in the Resapath program for non-ruminant calves (n=4148) and lambs (n=334), the percentage of susceptibility was 60% and 61%, respectively. This observation has already been explained with the existence of a resistant population highlighted by a bimodal distribution.

For *E. coli* from rabbits, according to data taken from the Resapath program, the percentage of susceptibility was only 34% (n=227).

For chickens and turkeys, data taken from the VetPath IV program (n=65) showed a susceptibility of *E. coli* of 83%.

4.3 Pharmacokinetics

The pharmacokinetic properties of sulfadiazine and trimethoprim are species dependent. With continuous administration in the drinking water, the steady-state concentrations are achieved in approximately 2 days.

Overall, sulfadiazine has almost complete and rapid oral absorption with very persistent plasma rates and oral bioavailability ranging between 80 to 90%, except in rabbits (29%). Its binding to plasma proteins varies between 28 to 80%, according to the species (28% pigs, 49% calves, 80% chickens). It presents a wide distribution in most tissues and organs in all species. Sulfadiazine is metabolised in the liver, and mainly excreted in the urine.

Trimethoprim is rapidly and well absorbed following oral administration with oral bioavailability ranging from 80 to 90%. Approximately 30% to 60% of trimethoprim is bound to plasma proteins, in percentages that vary according to the species (49% pigs, 57% calves, 77% chickens) and it presents a wide distribution in most tissues and organs in all species. Tissue concentrations, especially in lungs, liver and kidneys are often higher than the corresponding plasma concentrations. Trimethoprim is likely metabolised in the liver, and mainly excreted in the urine. The elimination rate of trimethoprim is generally faster than the one of sulfadiazine in all species.

Environmental properties
Trimethoprim is persistent in soils.

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 according to directions: 24 hours.
Shelf life after dilution in milk according to directions: 2 hours.

5.3 Special precautions for storage

Do not store above 25°C.
Store in a dry place.
Protect from light.

5.4 Nature and composition of immediate packaging

White opaque HPDE bottles or containers closed with a plastic screw cap.

Pack sizes:

Cardboard box containing one bottle of 100 mL.
Bottle of 250 mL.
Container of 2 L, 5 L.

Not all pack sizes may be marketed.

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

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Bottle of 250 ml
Container of 2 L, 5 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adjusol TMP SULFA Liquide 83.35 mg/ml + 16.65 mg/ml solution for use in drinking water/milk (FR)
Adjusol TMP SULFA 83.35 mg/ml + 16.65 mg/ml solution for use in drinking water/milk (GR)
Adjusol TMP SULFA Liquido 83.35 mg/ml + 16.65 mg/ml solution for use in drinking water/milk (PT)

2. STATEMENT OF ACTIVE SUBSTANCES

Each mL contains:
Sulfadiazine 83.35 mg
Trimethoprim 16.65 mg

3. PACKAGE SIZE

100 mL
250 mL
2 L
5 L

4. TARGET SPECIES

Pre-ruminant calves, pre-ruminant lambs, pigs, rabbits and chickens.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water/milk use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Calves
Meat and offal: 12 days.

Lambs
Meat and offal: 12 days.

Pigs

Meat and offal: 12 days.

Rabbits
Meat and offal: 12 days.

Chickens
Meat and offal: 12 days.
Eggs: Not for use in birds producing or intended to produce eggs for human consumption

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.
Once diluted in drinking water, use within 24 hours.
Once diluted in milk, use within 2 hours.

For 250 ml, 2 L, 5 L: Once opened use by…

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Store in a dry place.
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

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adjusol TMP SULFA liquide 83.35 mg/ml + 16.65 mg/ml solution for use in drinking water/milk (FR)
Adjusol TMP SULFA 83.35 mg/ml + 16.65 mg/ml solution for use in drinking water/milk (GR)
Adjusol TMP SULFA liquido 83.35 mg/ml + 16.65 mg/ml solution for use in drinking water/milk (PT)

2. STATEMENT OF ACTIVE SUBSTANCES

Each mL contains:
Sulfadiazine 83.35 mg
Trimethoprim 16.65 mg

3. TARGET SPECIES

Pre-ruminant calves, pre-ruminant lambs, pigs, rabbits and chickens.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

In drinking water/milk use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Calves
Meat and offal: 12 days.

Lambs
Meat and offal: 12 days.

Pigs
Meat and offal: 12 days.

Rabbits
Meat and offal: 12 days.

Chickens
Meat and offal: 12 days.
Eggs: Not for use in birds producing or intended to produce eggs for human consumption

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.
Once diluted in drinking water, use within 24h.
Once diluted in milk, use within 2h.

Once opened use by….

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Store in a dry place.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Adjusol TMP SULFA liquide 83.35 mg/ml + 16.65 mg/ml solution for use in drinking water/milk (FR)
Adjusol TMP SULFA 83.35 mg/ml + 16.65 mg/ml solution for use in drinking water/milk (GR)
Adjusol TMP SULFA liquido 83.35 mg/ml + 16.65 mg/ml solution for use in drinking water/milk (PT)

2. Composition

Each mL contains:

Active substances:
Sulfadiazine 83.35 mg
Trimethoprim 16.65 mg

Light yellow solution, slightly viscous.

3. Target species

Pre-ruminant calves, pre-ruminant lambs, pigs, rabbits and chickens

4. Indications for use

Pre-ruminant calves and lambs
Treatment and metaphylaxis of respiratory infections caused by *Pasteurella multocida* or *Mannheimia haemolytica* and infections caused by *Escherichia coli* susceptible to trimethoprim and sulfadiazine.

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

Pigs
Treatment and metaphylaxis of respiratory infections caused by *Pasteurella multocida* or *Actinobacillus pleuropneumoniae*, and infections caused by *Streptococcus suis* or *Escherichia coli* susceptible to trimethoprim and sulfadiazine.

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

Rabbits
Treatment and metaphylaxis of respiratory infections caused by *Pasteurella multocida*, and collibacillosis caused by *Escherichia coli* susceptible to trimethoprim and sulfadiazine.

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

Chickens
Treatment and metaphylaxis of collibacillosis caused by *Escherichia coli* susceptible to trimethoprim and sulfadiazine.

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

5. Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use in animals suffering from severe liver or kidney disease, oliguria or anuria.

6. Special warnings

Special warnings:
Severely diseased animals can have a decreased appetite and water consumption. If necessary the concentration of the veterinary medicinal product in the drinking water should be adjusted to make sure that the recommended dosage is being consumed.

Pigs, pre-ruminant calves, pre-ruminant lambs and rabbits: The uptake of medication by animals may be altered as a consequence of illness. In case of insufficient water uptake, animals should be treated parenterally instead using a suitable injectable veterinary medicinal product prescribed by the veterinarian.

Special precautions for safe use in the target species:
Due to the likely variability (time, geographical) in susceptibility of bacteria for potentiated sulfonamides, occurrence of resistance of bacteria may differ from country to country and even from farm to farm, and therefore bacteriological sampling and susceptibility testing are recommended. It is particularly of importance for *E. coli* infections where high percentages of resistance are observed.

Use of the veterinary medicinal product should be based on susceptibility testing of bacteria isolated from the animal. If not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Use of the veterinary medicinal product deviating from the instructions given in the Summary of product characteristics (SPC) may increase the prevalence of bacteria resistant to sulfadiazine and trimethoprim and may also decrease the effectiveness of combinations of trimethoprim with other sulfonamides due to the potential for cross-resistance.

Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.

To avoid deterioration of the kidneys due to crystalluria during treatment, it should be ensured that the animal receives sufficient amount of drinking water.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product contains sulfadiazine, trimethoprim and macrogol, which can cause allergic reactions in some people. Hypersensitivity to sulfonamides may lead to cross reactions with other antibiotics. Allergic reactions to these substances may occasionally be serious.

People with known hypersensitivity (allergy) to sulfonamides, trimethoprim or macrogol should avoid contact with the veterinary medicinal product.

This veterinary medicinal product may cause skin or eye irritation. During the preparation and administration of medicated drinking water, skin and eyes contact has to be avoided. Personal protective equipment consisting of waterproof gloves and safety glasses should be worn when handling the veterinary medicinal product. In case of accidental contact with the eyes or skin, wash the

affected area with plenty of water, and if skin rash occurs, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

This veterinary medicinal product may be harmful if ingested. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
Laboratory studies in rats and rabbits have shown evidence of teratogenic and foetotoxic effects.

Do not use during pregnancy and lactation.

Laying birds:
Do not use in birds in lay.

Interaction with other medicinal products and other forms of interaction:
Do not administer concomitantly with coccidiostats or veterinary medicinal products containing sulfonamides.
Do not associate with PABA (para-aminobenzoic acid).
Sulfonamides potentiate anticoagulants action.

Overdose:
Sulfonamides overdose causes renal toxicity. In this case, the administration of the veterinary medicinal product has to be stopped.

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

7. Adverse events

Pre-ruminant calves, pre-ruminant lambs, pigs, rabbits and chickens:

Very rare (<1 animal / 10, 000 animals treated, including isolated reports):
Decreased drinking[1]
Undetermined frequency (cannot be estimated from the available data):
Hypersensitivity reaction

[1] In chickens

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 its local representative 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

Administration route:

For oral use in drinking water/milk replacer.

Amounts to be administered:

Pre-ruminant calves and lambs

12.5 mg of sulfadiazine and 2.5 mg of trimethoprim per kg body weight (corresponding to 1.5 ml of solution per 10 kg body weight), every 12 hours for 4 to 7 consecutive days, to be mixed with the milk replacer (when adding the water).

Pigs, rabbits

25 mg of sulfadiazine and 5 mg of trimethoprim per kg of live weight per day (corresponding to 3 mL of solution per 10 kg live weight per day in continuous) for 4 to 7 consecutive days, to be diluted in drinking water.

Chickens

25 mg of sulfadiazine and 5 mg of trimethoprim per kg of live weight per day (corresponding to 0.3 mL of solution per kg of live weight per day in continuous), for 4 to 7 consecutive days, to be diluted in drinking water.

Guidance for preparing product solutions:

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing. The intake of medicated water depends on the physiological and clinical condition of the animals. In order to obtain the correct dosage, the concentration of sulfadiazine and trimethoprim may need to be adjusted accordingly.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{Dose (mg product per kg body weight per day)} \times \text{Mean body weight (kg) of animals to be treated}}{\text{Mean daily water consumption (litre) per animal per day}} = \text{___ mg product per litre of drinking water/milk}$$

9. Advice on correct administration

The medicated drinking water should be the sole source of drinking water for the treatment duration.

Any medicated drinking water which is not consumed within 24 hours should be discarded.

10. Withdrawal periods

Calves

Meat and offal: 12 days.

Lambs

Meat and offal: 12 days.

Pigs

Meat and offal: 12 days.

Rabbits

Meat and offal: 12 days.

Chickens

Meat and offal: 12 days.
Eggs: Not for use in birds producing or intended to produce eggs for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C.
Store in a dry place
Protect from light.

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.

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 dilution in milk according to directions: 2 hours.

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 systems. 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

Cardboard box containing one bottle of 100 mL.
Bottle of 250 ml.
Container of 2 L, 5 L.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

VIRBAC
1ère avenue 2065 m L I D
06516 Carros
France

Manufacturer responsible for batch release:

VIRBAC
1ère avenue 2065 m L I D
06516 Carros
France

Or

FC France SAS
8 rue des Aulnaies
95420 Magny-en-Vexin
France

Local representatives and contact details to report suspected adverse events:

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

17. Other information

Environmental properties
Trimethoprim is persistent in soils.