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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for use in drinking water/milk.
Light yellow solution, slightly viscous.

4. CLINICAL PARTICULARS

4.1. Target species

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

4.2. Indications for use, specifying the 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 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 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 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 product is used.

4.3. 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.

4.4. Special warnings for each target species

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 product prescribed by the veterinarian.

4.5. Special precautions for use

Special precautions for use in animals
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 5.1).

Use of the 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 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 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 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.

4.6. Adverse effects (frequency and severity)

Reduced water intake has been reported in very rare cases in chickens.

Hypersensitivity reactions have been described in literature.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7. Use during pregnancy, lactation or lay

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

Do not use during pregnancy and lactation, or lay.

4.8. 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.

4.9. Amounts to be administered and administration route

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 the 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 should be adjusted accordingly.

The dosage of the product to be incorporated should be established 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.

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

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

4.11. Withdrawal period(s)

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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: anti-infectives for systemic use.
ATCvet code: QJ01EW10.

5.1. Pharmacodynamic properties

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%.

5.2. Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Macrogol 200
Sodium hydroxide (for pH adjustment)
Purified water

6.2. Major incompatibilities

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: 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.

6.4. Special precautions for storage

Store in a dry place.
Protect from light.

6.5. Nature and composition of immediate packaging

Polyethylene bottles or containers closed with a plastic screw cap.

Pack sizes:

Cardboard box containing one bottle of 100 mL, 250 mL, 500 mL or 1 L.
Container of 2 L, 5 L, 10 L.

Not all pack sizes may be marketed.

6.6. Special precautions for the disposal of unused veterinary medicinal products 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

VIRBAC
1ère Avenue - 2065 m - LID
06516 Carros
France

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

To be completed nationally.

10. DATE OF REVISION OF THE TEXT

To be completed nationally.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Cardboard box and bottle of 100 mL, 250 mL, 500 mL or 1 L

Container of 2 L, 5 L, 10 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:
83.35 mg of sulfadiazine
16.65 mg of trimethoprim

3. PHARMACEUTICAL FORM

Solution for use in drinking water/milk.

4. PACKAGE SIZE

100 mL
250 mL
500 mL
1 L
2 L
5 L
10 L

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once opened use within 3 months.

11. SPECIAL STORAGE CONDITIONS

Store in a dry place.
Protect from light.

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

Disposal: read package leaflet.

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère Avenue - 2065 m - LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
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)

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

Marketing authorisation holder:
VIRBAC
1ère Avenue - 2065 m - LID
06516 Carros
France

Manufacturer responsible for batch release:
VIRBAC
1ère Avenue - 2065 m - LID
06516 Carros
France

Or

FC France SAS
8 rue des aulnaies
95420 Magny en Vexin
France

2. 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)
Sulfadiazine
Trimethoprim

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

Each mL contains:

Active substances:
Sulfadiazine 83.35 mg
Trimethoprim 16.65 mg

Light yellow solution, slightly viscous.

4. INDICATION(S)

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 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 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 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 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. ADVERSE REACTIONS

Reduced water intake has been reported in very rare cases in chickens.

Hypersensitivity reactions have been described in literature.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 the 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 should be adjusted accordingly.

The dosage of the product to be incorporated should be established 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 PERIOD(S)

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.
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 container: 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 WARNING(S)

Special warnings for each target species:
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, 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 product prescribed by the veterinarian.

Special precautions for use in animals:
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 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 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 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 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. Wear personal protective equipment consisting of waterproof gloves and safety glasses 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, lactation or lay:
Laboratory studies in rats and rabbits have shown evidence of teratogenic and foetotoxic effects.

Do not use during pregnancy and lactation, or 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).

Sulfamides potentiate anticoagulants action.

Overdose (symptoms, emergency procedures, antidotes):
Sulfonamides overdose causes renal toxicity. In this case, the administration of the product has to be stopped.

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

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<DD/MM/YYYY>
To be completed nationally.

15. OTHER INFORMATION

Pack sizes:

Cardboard box containing one bottle of 100 mL, 250 mL, 500 mL or 1 L.

Container of 2 l, 5 l, 10 L.

Not all pack sizes may be marketed.