ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Reconcile 8 mg chewable tablets for dogs
Reconcile 16mg chewable tablets for dogs
Reconcile 32 mg chewable tablets for dogs
Reconcile 64 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each tablet contains:

Reconcile 8 mg: Fluoxetine 8 mg (equivalent to 9.04 mg fluoxetine hydrochloride)
Reconcile 16mg: Fluoxetine 16 mg (equivalent to 18.08mg fluoxetine hydrochloride)
Reconcile 32 mg: Fluoxetine 32 mg (equivalent to 36.16 mg fluoxetine hydrochloride)
Reconcile 64 mg: Fluoxetine 64 mg (equivalent to 72.34 mg fluoxetine hydrochloride)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablet.
Speckled, tan to brown round chewable tablets, embossed on one side with a number (as listed below):
Reconcile 8 mg tablets: 4203
Reconcile 16 mg tablets: 4205
Reconcile 32 mg tablets: 4207
Reconcile 64 mg tablets: 4209

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

As an aid in the treatment of separation-related disorders in dogs manifested by destruction and inappropriate behaviours (vocalisation and inappropriate defaecation and/or urination) and only in combination with behavioural modification techniques.

4.3 Contraindications

Do not use in dogs weighing less than 4 kg.

Do not use in dogs with epilepsy or in dogs with a history of seizures.

Do not use in case of hypersensitivity to fluoxetine or other Selective Serotonin Re-Uptake Inhibitors (SSRIs) or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

The safety of the product has not been established in dogs less than 6 months of age or weighing less than 4 kg.

Though rare, seizures may occur in dogs treated with Reconcile. Treatment should be stopped if seizures occur.

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

In case of accidental self-ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. In humans, the most common symptoms associated with overdose include seizures, somnolence, nausea, tachycardia, and vomiting.

4.6 Adverse reactions (frequency and seriousness)

To minimize the risk of adverse reactions, the recommended dose should not be exceeded.

- Decreased appetite (including anorexia); lethargy (very common).
- Urinary tract disorders (cystitis, urinary incontinence, urinary retention, stranguria); central nervous system signs (incoordination, disorientation) (common).
- Weight loss/loss of condition; mydriasis (uncommon).
- Panting, seizures, vomiting (rare).

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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation, thus the use is not recommended during pregnancy and lactation.

Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effect. No effect on the reproductive capacity in male and female rats was noted.

Do not use in breeding animals.

4.8 Interaction with other medicinal products and other forms of interaction

Reconcile should not be given concomitantly with veterinary medicinal products that lower the seizure threshold (e.g. phenothiazines such as acepromazine or chlorpromazine).

Do not use the product in conjunction with other serotonergic agents (e.g. sertraline) and monoamine oxidase inhibitors (MAOIs) [e.g., selegiline hydrochloride (L-deprenyl), amitraz] or tricyclic amines (TCAs) (e.g. amitriptyline and clomipramine).

A 6-week washout interval should be observed following discontinuation of therapy with the product prior to the administration of any veterinary medicinal product that may adversely interact with fluoxetine or its metabolite, norfluoxetine.

Fluoxetine is largely metabolised by the P-450 enzyme system, although the precise isoform in dogs is unknown. Therefore, fluoxetine should be used with caution with other veterinary medicinal products.

4.9 Amounts to be administered and administration route

Reconcile should be administered orally at a once daily dose of 1 to 2 mg/kg bodyweight according to the dosage table below:

Bodyweight (kg)	Tablet strength (mg)	Number of tablets per day
4 - 8	Reconcile 8mg tablet	1
> 8 - 16	Reconcile 16mg tablet	1
> 16 - 32	Reconcile 32mg tablet	1
> 32 - 64	Reconcile 64mg tablet	1

Clinical improvement with the product is expected within 1 to 2 weeks. If no improvement is noted within 4 weeks, case management should be re-evaluated. Clinical studies have shown that a beneficial response has been demonstrated for up to 8 weeks treatment with fluoxetine.

Reconcile tablets may be given with or without food. The tablets are flavoured and most dogs will consume the tablet when offered by the owner.

If a dose is missed, the next scheduled dose should be administered as prescribed. At the end of treatment it is not necessary to taper or reduce doses because of the long half-life of this veterinary medicinal product.

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

At doses in excess of the recommended dose, observed side effects at the therapeutic dose, including seizures, are exacerbated. In addition, aggressive behaviour was observed. In clinical studies these side effects were stopped immediately upon intravenous administration of a standard dose of diazepam.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: selective serotonin reuptake inhibitors (SSRI)
ATCvet code: QNO6ABO3

5.1 Pharmacodynamic properties

Fluoxetine and its active metabolite nor-fluoxetine have been shown to be highly selective inhibitors of serotonin uptake both *in vitro* and *in vivo.* Fluoxetine does not act as a sedative. Fluoxetine inhibits catecholamine uptake only at high concentrations *in vitro* and has no effect on catecholamine uptake *in vivo* at doses that are used to inhibit serotonin uptake. As a result of inhibiting serotonin uptake, fluoxetine enhances serotonergic neurotransmission and produces functional effects resulting from increased activation of serotonin receptors. Fluoxetine lacks any significant affinity for neurotransmitter receptors, including the muscarinic cholinergic receptor, adrenergic receptors, or histaminergic H1 receptors, and does not have direct effects on the heart.

5.2 Pharmacokinetic particulars

Fluoxetine is well absorbed after oral administration (approximately72%) and the absorption is not affected by feeding. Fluoxetine is metabolised to norfluoxetine, an equipotent SSRI that contributes to the efficacy of the veterinary medicinal product.

In a 21 day study, fluoxetine was administered daily at a dose of 0.75, 1.5 and 3.0 mg/kg body weight to laboratory Beagles. The maximum plasma concentration (C_{max}) and area under the plasma concentration time curve (AUC) for fluoxetine were approximately dose proportional between 0.75 and 1.5 mg/kg, with a greater than dose proportional increase at 3 mg/kg. After administration, fluoxetine readily appeared in plasma with mean T_{max} values ranging from 1.25 to 1.75 hours on day 1 and from 2.5 to 2.75 hours on day 21. Plasma levels readily declined with mean $t_{½}$ values ranging from 4.6 to 5.7 hours on day 1 and from 5.1 to 10.1 hours on day 21. Norfluoxetine plasma levels slowly appeared in plasma and were slowly eliminated with $t_{½}$ values ranging from 44.2 to 48.9 hours on day 21. Norfluoxetine C_{max} and AUC were generally dose proportional but these values were 3 to 4 fold higher on day 21 than on day 1.

Accumulation of fluoxetine and norfluoxetine occurred following multiple doses until reaching a steady-state within approximately 10 days. Following the last dose administration, fluoxetine and norfluoxetine plasma levels declined steadily in a log-linear fashion. Elimination studies in dogs have shown that 29.8% and 44% of the dose were excreted in urine and faeces, respectively by 14 days following dosing.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Sucrose (as compressible sugar)
Crospovidone
Artificial beef flavour
Silica, colloidal anhydrous
Calcium hydrogen phosphate dihydrate
Magnesium stearate

6.2 Major incompatibilities

Not applicable.

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: 30 days.
Discard any tablets remaining in the container after the shelf life has expired.

6.4. Special precautions for storage

Do not store above 30 °C.
Store in the original container. Keep the bottle tightly closed in order to protect from moisture.
Do not remove the desiccant.

6.5 Nature and composition of immediate packaging

White high density polyethylene (HDPE) bottle with a child resistant closure, cotton coil and a desiccant pack.

Each bottle contains 30 tablets.
Pack size of one bottle.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

FORTE Healthcare ltd
Cougar Lane
Naul
Co. Dublin
Ireland

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/080/001 - 004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08/07/2008
Date of last renewal: 13/07/2018

10 DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Tairgi Tread -Lia Baile na Sceilge Teo T/A Ballinskelligs
Veterinary Products,
Ballinskelligs,
Co. Kerry,
V23 XR52,
Ireland

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton 8mg, 16 mg, 32 mg and 64 mg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Reconcile 8 mg chewable tablets for dogs
Reconcile 16mg chewable tablets for dogs
Reconcile 32 mg chewable tablets for dogs
Reconcile 64 mg chewable tablets for dogs

fluoxetine

2. STATEMENT OF ACTIVE SUBSTANCES

8 mg fluoxetine (as 9.04 mg fluoxetine hydrochloride)
16mg fluoxetine (as 18.08mg fluoxetine hydrochloride)
32 mg fluoxetine (as 36.16 mg fluoxetine hydrochloride)
64 mg fluoxetine (as 72.34 mg fluoxetine hydrochloride)

3. PHARMACEUTICAL FORM

Chewable tablet.

4. PACKAGE SIZE

Each bottle contains 30 tablets.

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 30 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
Store in the original container.
Keep the bottle tightly closed in order to protect from moisture.
Do not remove the desiccant.

12. SPECIFIC 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

FORTE Healthcare ltd
Cougar Lane
Naul
Co. Dublin
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/080/001
EU/2/08/080/002
EU/2/08/080/003
EU/2/08/080/004

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle label -8 mg, 16 mg, 32 mg, 64 mg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Reconcile 8 mg chewable tablets for dogs
Reconcile 16mg chewable tablets for dogs
Reconcile 32 mg chewable tablets for dogs
Reconcile 64 mg chewable tablets for dogs

fluoxetine

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

8 mg fluoxetine (as 9.04 mg fluoxetine hydrochloride)
16mg fluoxetine (as 18.08mg fluoxetine hydrochloride)
32 mg fluoxetine (as 36.16 mg fluoxetine hydrochloride)
64 mg fluoxetine (as 72.34 mg fluoxetine hydrochloride)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

30 tablets.

4. ROUTE(S) OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once opened, use by….

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Reconcile 8 mg chewable tablets for dogs
Reconcile 16 mg chewable tablets for dogs
Reconcile 32 mg chewable tablets for dogs
Reconcile 64 mg chewable tablets for dogs

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

Marketing authorisation holder:

FORTE Healthcare ltd
Cougar Lane
Naul
Co. Dublin
Ireland

Manufacturer responsible for batch release:

Tairgi Tread -Lia Baile na Sceilge Teo T/A Ballinskelligs
Veterinary Products,
Ballinskelligs,
Co. Kerry,
V23 XR52,
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Reconcile 8 mg chewable tablets for dogs
Reconcile 16 mg chewable tablets for dogs
Reconcile 32 mg chewable tablets for dogs
Reconcile 64 mg chewable tablets for dogs

fluoxetine

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

Each tablet contains:

Reconcile 8 mg: fluoxetine 8 mg (equivalent to 9.04 mg fluoxetine hydrochloride)
Reconcile 16mg: fluoxetine 16 mg (equivalent to 18.08mg fluoxetine hydrochloride)
Reconcile 32 mg: fluoxetine 32 mg (equivalent to 36.16 mg fluoxetine hydrochloride)
Reconcile 64 mg: fluoxetine 64 mg (equivalent to 72.34 mg fluoxetine hydrochloride)

Speckled, tan to brown round chewable tablets, embossed on one side with a number (as listed below):
Reconcile 8 mg tablets: 4203
Reconcile 16 mg tablets: 4205
Reconcile 32 mg tablets: 4207
Reconcile 64 mg tablets: 4209

4. INDICATION(S)

As an aid in the treatment of separation-related disorders in dogs, such as destruction and vocalisation and inappropriate defaecation and/or urination. This product should only be used in conjunction with a behaviour modification programme recommended by your veterinary surgeon.

5. CONTRAINDICATIONS

Do not use in dogs weighing less than 4 kg.

Do not use in dogs with epilepsy or a history of seizures.

Do not use in case of hypersensitivity to fluoxetine or other Selective Serotonin Re-Uptake Inhibitors (SSRIs) or to any of the excipients.

6. ADVERSE REACTIONS

To minimize the risk of adverse reactions, the recommended dose should not be exceeded.

- Decreased appetite (including anorexia); lethargy (including calmness and increased sleeping) (very common)
- Urinary tract disorders (such as bladder infections, irregular urination, discomfort in passing urine); central nervous system signs (incoordination, disorientation) (common)
- Weight loss/loss of condition; dilation of the pupils of the eye (uncommon)
- Panting, seizures, vomiting (rare)

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

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Reconcile should be administered orally at a once daily dose of 1 to 2 mg/kg bodyweight according to the dosage table below:

Body weight (kg)	Tablet strength (mg)	Number of tablets per day
4-8	Reconcile 8 mg tablet	1
>8-16	Reconcile 16 mg tablet	1
>16-32	Reconcile 32 mg tablet	1
>32-64	Reconcile 64 mg tablet	1

Clinical improvement with the product is expected within 1 or 2 weeks. If no improvement is noted within 4 weeks, consult your veterinary surgeon who will need to re-evaluate the dog’s treatment.

Clinical studies have shown that a beneficial response has been demonstrated for up to 8 weeks treatment with fluoxetine.

If a dose is missed, the next scheduled dose should be administered as prescribed.

9. ADVICE ON CORRECT ADMINISTRATION

Tablets should be administered orally with or without food and are flavoured so that most dogs will consume the tablet when offered by the owner.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store above 30°C. Store in the original container. Keep the bottle tightly closed in order to protect from moisture. Do not remove the desiccant.

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle.
Shelf-life after first opening the container: 30 days.
Discard any tablets remaining 30 days after opening.

12. SPECIAL WARNING(S)

Special warnings for each target species:

The safety of Reconcile has not been established in dogs less than 6 months of age or weighing less than 4 kg.

Though rare, seizures may occur in dogs treated with the product. Treatment should be stopped if seizures occur.
Tablets should not be used in dogs with epilepsy or a history of seizures

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

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician. In humans, the most common symptoms associated with overdosage include seizures, somnolence, nausea, tachycardia, and vomiting.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation, thus the use is not recommended during pregnancy and lactation.

Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effect. No effect on the reproductive capacity in male and female rats was noted.

Do not use in breeding animals.

Interaction with other medicinal products and other forms of interaction:

Please inform your veterinary surgeon if your dog is receiving, or has had, any other medicines, even those not prescribed, as the product should not be given at the same time as many other medicines.

Reconcile should not be given concomitantly with veterinary medicinal products that lower the seizure threshold (e.g. phenothiazines such as acepromazine or chlorpromazine).

Do not use the product in conjunction with other serotonergic agents (e.g. sertraline) and monoamine oxidase inhibitors (MAOIs) [e.g., selegiline hydrochloride (L-deprenyl), amitraz] or tricyclic amines (TCAs) (e.g. amitriptyline and clomipramine).

A 6-week washout interval should be observed following discontinuation of therapy with the product prior to the administration of any veterinary medicinal product that may adversely interact with fluoxetine or its metabolite, norfluoxetine.

Fluoxetine is largely metabolised by the liver. Therefore, fluoxetine should be used with caution with other veterinary medicinal products.

Overdose (symptoms, emergency procedures, antidotes):

In cases of accidental overdose your veterinary surgeon should be consulted immediately and symptomatic therapy should be initiated. Adverse reactions as described above, including seizures, are more common after overdose. In addition, aggressive behaviour was observed.

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

Any unused product or waste material should be disposed of in accordance with local requirements. 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

Pack sizes:
One bottle per carton.
The tablets are packaged in HDPE bottles, each bottle containing 30 tablets with a cotton coil and desiccant pack.

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