ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. 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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

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

Excipients:

Qualitative composition of excipients and other constituents
Microcrystalline cellulose
Sucrose (as compressible sugar)
Crospovidone
Artificial beef flavour
Silica, colloidal anhydrous
Calcium hydrogen phosphate dihydrate
Magnesium stearate

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each 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.

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 the veterinary medicinal product. 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 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: Dogs

Very common (>1 animal / 10 animals treated):	Decreased appetite (including anorexia) Lethargy
Common (1 to 10 animals / 100 animals treated):	Urinary tract disorders (cystitis, urinary incontinence, urinary retentions, stranguria) Central nervous system signs (incoordination, disorientation)
Uncommon (1 to 10 animals / 1 000 animals treated):	Weight loss/loss of condition Mydriasis
Rare (1 to 10 animals / 10 000 animals treated):	Panting Seizures Vomiting
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	

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

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

Pregnancy and lactation:

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.

Fertility:

Do not use in breeding animals.

3.8 Interaction with other medicinal products and other forms of interaction

The veterinary medicinal product 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.

3.9 Administration routes and dosage

The veterinary medicinal product 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.

The veterinary medicinal product 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.

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

At doses in excess of the recommended dose (in excess of 1 to 2 mg/kg bodyweight), 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.

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

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN06AB03

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

Fluoxetine is well absorbed after oral administration (approximately 72%) 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 30 days.
Discard any tablets remaining in the container after the shelf life has expired.

5.3 Special precautions for storage

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

5.4 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 chewable tablets.
Pack size of one bottle.

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

FORTE Healthcare Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/080/001 - 004

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 08/07/2008.

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

{MM/YYYY}

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 II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each chewable tablet contains:

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

3. PACKAGE SIZE

30 chewable tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 30 days.

9. SPECIAL STORAGE PRECAUTIONS

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

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

FORTE Healthcare Ltd.

14. MARKETING AUTHORISATION NUMBERS

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

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle Label – 8 mg, 16 mg, 32 mg, and 64 mg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Reconcile
Reconcile
Reconcile
Reconcile

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each chewable tablet contains:

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 30 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. 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

2. Composition

Each tablet contains:

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

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

3. Target species

Dogs

4. Indications for use

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. Special warnings

None.

Special precautions for safe use in the target species:

The safety of the veterinary medicinal 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 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 teratogenic, foetotoxic, or maternotoxic effects. 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.

The veterinary medicinal product 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.

Overdose:

In cases of accidental overdose your veterinary surgeon should be consulted immediately, and symptomatic therapy should be initiated. Adverse reactions as described below, including seizures, are more common after overdose. In addition, aggressive behaviour was observed. In clinical studies these effects were stopped immediately upon intravenous administration of a standard dose of diazepam.

7. Adverse events

Target species: Dogs

Very common (> 1 animal / 10 animals treated):
Decreased appetite (including anorexia); lethargy (including calmness and increased sleeping)
Common (1 to 10 animals / 100 animals treated):

Urinary tract disorders (such as bladder infections, irregular urination, discomfort in passing urine); central nervous system signs (incoordination, disorientation)
Uncommon (1 to 10 animals / 1 000 animals treated):
Weight loss/loss of condition; dilation of the pupils of the eye
Rare (1 to 10 animals / 10 000 animals treated):
Panting, seizures, vomiting

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

The veterinary medicinal product 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, 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.

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.

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 periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Store below 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 outer carton and the bottle. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 30 days.
Discard any tablets remaining 30 days after opening.

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 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

EU/2/08/080/001 – 004

Each bottle contains 30 chewable tablets, is packed in a carton box.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:

FORTE Healthcare Ltd.
Cougar Lane
Naul
Co. Dublin
Ireland

Manufacturer responsible for batch release and contact details to report suspected adverse events:

FORTE Healthcare Ltd.
Block 3, Unit 9,
CityNorth Business Campus,
Stamullen, Co. Meath,
K32 D990, Ireland
Tel: + 35318417666
enquiries@fortehealthcare.com

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.

België/Belgique/Belgien Kela Veterinaria nv BE-Tel +32 (0)3 780 63 90 info.vet@kela.health	**Nederland** Virbac Nederland BV Hermesweg 15 NL-3771ND Barneveld Tel +31 342 427 127 info@virbac.nl
Danmark Salfarm Danmark A/S Fabriksvej 30 DK-6000 Kolding Tlf: +45 7552 9413 info@salfarm.com	**Norge** Salfarm Scandinavia AS Fridtjof Nansens Plass 4 NO-0160 Oslo Tel: +47 902 97 102 norge@salfarm.com
Deutschland Virbac Tierarzneimittel GmbH Rögen 20, DE-23843 Bad Oldesloe Tel: +49 4531 805 111 info@virbac.de	**Österreich** Florian Schaible GmbH – PowerVet Rosenbach 121 AT-9183 Rosenbach Tel: +43 4253/31095 office@powervet.at
España VETNOVA SALUD S.L. c/ Fuente del toro, 21. Nave 3. ES-28710 El Molar. Tel: + 34 918 440 273 vetnova@vetnova.net	**Portugal** VETNOVA SALUD S.L. c/ Fuente del toro, 40. Nave 3. 28710 El Molar. Espanha Tel: +351 938 116 105 vetnova@vetnova.net
France Axience SAS Tour Essor – 14, rue Scandicci FR-93500 Pantin Tél: +33 (0)1 41 83 23 10 contact@axience.fr	**Suomi/Finland** Vetcare Finland Oy Hiomotie 3 A 5 FI-00380 Helsinki/Helsingfors Puh/Tel: +358 201 443 360 vetcare@vetcare.fi
Italia VETNOVA SALUD S.L. c/ Fuente del toro, 40. Nave 3. IT-28710 El Molar. Spagna Tel: + 39 3664 303226 vetnova@vetnova.net	**Sverige** Salfarm Scandinavia AB Florettgatan 29C, 2. Vån. SE-254 67 Helsingborg Tel: +46 (0) 767 834 810 scan@salfarm.com
Luxembourg/Luxemburg Kela Veterinaria nv Belgique/Belgien Tel +32 (0)3 780 63 90 info.vet@kela.health	**United Kingdom (Northern Ireland)** Forte Healthcare Ltd Block 3, Unit 9, CityNorth Business Campus Stamullen, Co. Meath, K32 D990, Ireland

	Tel: +441292800013 enquiries@fortehealthcare.com