SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Reconcile 16 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substance:

16 mg: Fluoxetine 16 mg (equivalent to 18.08 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 4205.

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 4kg.
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 4kg.

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 retention, 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

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 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 teratogenic, foetotoxic, or maternotoxic effects. 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 if 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 concentration *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 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 T½ 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 day1.

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.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

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 Limited

7. MARKETING AUTHORISATION NUMBER

Vm 27819/5003

8. DATE OF FIRST AUTHORISATION

8 July 2008

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

November 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall
Approved: 04 November 2025