PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Outer Carton - 8 mg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Reconcile 8 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

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 60 days.

9. SPECIAL STORAGE PRECAUTIONS

Store below 30 °C.
Store in the original container.
Keep the bottle tightly closed in order to protect 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 Limited

14. MARKETING AUTHORISATION NUMBER

Vm 27819/5002

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle label – 8 mg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Reconcile

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each chewable tablet contains:
8 mg fluoxetine (as 9.04 mg fluoxetine hydrochloride)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 60 days

PARTICULARS TO APPEAR ON THE 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

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) and scored on one side:
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 4kg.
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 4kg.

Though rare, seizures may occur in dogs treated with the veterinary medicinal 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 the label to the physician. In humans, the most common symptoms associated with overdose 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 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.

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 liver. 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 above, 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 using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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: 60 days
Discard any tablets remaining 60 days after opening

12. Special precautions for disposal

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 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

Vm 27819/5002
Vm 27819/5003

Vm 27819/5004
Vm 27819/5005

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

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder:

Forte Healthcare Limited
Cougar Lane
Hazardstown
Naul
Co. Dublin
K32 FH74
Ireland

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

FORTE Healthcare Ltd,
Block 3 Unit 9,
CityNorth Business Campus,
Stamullen, Co. Meath,
K32 D990, Ireland
Tel: +441292800013
enquiries@fortehealthcare.com

17. Other information

POM-V	Veterinary medicinal product subject to prescription

Gavin Hall
Approved: 08 March 2026