ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fluoxevet 32 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains :
Fluoxetine…….. 32.0 mg
(equivalent to 35.80 fluoxetine hydrochloride)

3. PACKAGE SIZE

30 tablets

4. TARGET SPECIES

Dog

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 120 days.

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package.
Any remaining portions of divided tablets should be replaced in the bottle, which should be returned to the cardboard box. Remaining tablet portions should be given at the next administration.

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

DOMES PHARMA

14. MARKETING AUTHORISATION NUMBERS

Vm 54982/3007

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fluoxevet

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

32 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Fluoxevet 32 mg tablets for dogs

2. Composition

Each tablet contains:

Active substance:
Fluoxetine…….. 32.0 mg
(equivalent to 35.80 mg fluoxetine hydrochloride)

White to cream, spotted, round convex tablet with a cross-shaped break.
The tablets can be divided into 2 or 4 equal parts.

3. Target species

Dog.

4. Indications for use

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.

5. 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 cases of hypersensitivity to the active substance or other Selective Serotonin Re-Uptake Inhibitors (SSRIs) or to any of the excipients.

6. Special warnings

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.

As tablets are flavoured, store tablets out of reach of the animals in order to avoid accidental ingestion.

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 humans, the most common symptoms associated with overdose include seizures, somnolence, nausea, tachycardia, and vomiting.
To avoid accidental ingestion, particularly by a child, unused tablet parts should immediately be returned to the bottle, the child-resistant closure replaced and the product stored safely out of the sight and the reach of children. Any uneaten medicated food must be disposed of immediately and the bowl washed thoroughly.
In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the physician.
A risk of congenital malformations was observed in infants with mothers exposed to fluoxetine in early pregnancy. Pregnant women should avoid prolonged skin contact with the product.
The active substance fluoxetine may cause eye-irritation. Therefore, hand-to-eye contact should be avoided. In case of accidental contact with eyes, rinse immediately with plenty of water.
Wash hands after use.

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.

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.

Fertility:
Do not use in breeding animals.

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 veterinary medicinal 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 veterinary medicinal 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:
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.

7. Adverse events

In dogs:

Very common (> 1 animal / 10 animals treated):

Decreased appetite or appetite loss; lethargy (including calmness and increased sleeping)

Common (1 to 10 animals / 100 animals treated):

Bladder infections, irregular urination, discomfort in passing urine; Incoordination, disorientation

Uncommon (1 to 10 animals / 1,000 animals treated):

Weight loss/loss of condition; Dilatation of the pupils of the eye

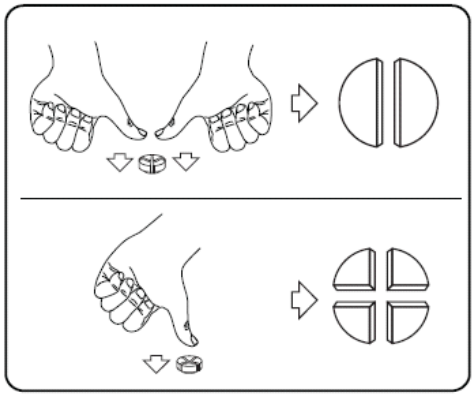
Rare (1 to 10 animals / 10,000 animals treated):

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 either the marketing authorisation holder or the local representative of the marketing authorisation holder 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

Oral use.
The veterinary medicinal product should be administered orally at a once daily dose of 1 to 2 mg/kg bodyweight.
Tablets can be divided into 2 or 4 equal parts to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



2 equal parts: press down with your thumbs on both sides of the tablet.
4 equal parts: press down with your thumb in the middle of the tablet.

Clinical improvement with the veterinary medicinal 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 tablets may be given with or without food.
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

None.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Store in the original package.
Any remaining portions of divided tablets should be replaced in the bottle, which should be returned to the cardboard box. Remaining tablet portions should be given at the next administration.
Do not use this veterinary medicinal product after the expiry date which is stated on the bottle after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 120 days.

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 or pharmacist 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

Marketing authorisation numbers:

Vm 54982/3007

Pack size:
Cardboard box of one bottle of 30 tablets

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 <and contact details to report suspected adverse reactions>:
DOMES PHARMA
3 rue André Citroën
63430 Pont-du-Château
France

Manufacturer responsible for batch release:
EUROPHARTECH
34 rue Henri Matisse
63370 Lempdes
France

<Local representatives <and contact details to report suspected adverse reactions>:>
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

[For MRP/DCP/SRP and national procedures: To be completed nationally.]"

Gavin Hall

Approved: 09 August 2024