

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

10 tablets

100 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SEMELCEF 200 mg tablets for dogs and cats (AT, BE, CY, CZ, EE, EL, ES, HR, HU, IE, PL, PT, SI, SK)

Cefadroxil

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Active substance: Cefadroxil 200 mg (equivalent to Cefadroxil monohydrate 210 mg).

3. PHARMACEUTICAL FORM

Tablet.

4. PACKAGE SIZE

10 tablets

100 tablets

5. TARGET SPECIES

Dogs and cats

6. INDICATION

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7. METHOD AND ROUTE OF ADMINISTRATION

Route of administration: oral use

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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9. SPECIAL WARNING, IF NECESSARY

Penicillins/cephalosporins may occasionally cause severe allergic reactions.
Read the package leaflet before use.

10. EXPIRY DATE

EXP. {month/year}
Shelf-life of the divided tablet after first use of the primary packaging: 3 days.

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.
Keep every part of the divided tablet in the blister and use at time of next administration.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

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

SUPPORT PHARMA, S.L.
General Alvarez de Castro, 39
28010 Madrid, Spain

16. MARKETING AUTHORISATION NUMBERS

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS
Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SEMELCEF 200 mg tablets for dogs and cats (AT, BE, CY, CZ, EE, EL, ES, HR, HU, IE, PL, PT, SI, SK)
Cefadroxil

2. NAME OF THE MARKETING AUTHORISATION HOLDER

SUPPORT PHARMA, S.L.

3. EXPIRE DATE

EXP. {month/year}

4. BATCH NUMBER

Batch {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.