

[Version 8.1,01/2017]

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton boxes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIXIE 402 mg spot-on solution for very large dogs
Fipronil

2. STATEMENT OF ACTIVE SUBSTANCES

Each pipette of 4.02 ml contains: Fipronil 402 mg

3. PHARMACEUTICAL FORM

Spot on solution.

4. PACKAGE SIZE

Package sizes:

1,2,3,4,5,6,8,10,12,24,30,60,90,120 or 150 pipettes in carton box

5. TARGET SPECIES

Dogs 40-60 kg

6. INDICATION(S)

Treatment of existing flea (*Ctenocephalides felis*) infestations and prevention of re-infestation with fleas through insecticidal effect for up to 5 weeks. in dogs. One application provides immediate and persistent insecticidal efficacy and prevents new infestations by fleas up to a maximum of 5 weeks.

The product prevents new infestations of *Rhipicephalus sanguineus* ticks from day 9 to day 23 after product application. The product has not demonstrated an immediate acaricidal effect, if ticks of these species are present when the product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week.

The product has not demonstrated an immediate acaricidal effect against ticks but prevents new infestations of *Rhipicephalus sanguineus* ticks from day 9 to day 23 after product application. If ticks of these species are present when the product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week.

The medication can be used as part of the strategy in the treatment of flea allergy dermatitis (FAD).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>

11. SPECIAL STORAGE CONDITIONS

Store in the original package
Store below 30°C

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

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

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

QUIMICA DE MUNGUÍA S.A.
Derio Bidea, 51
48100 Munguía- Vizcaya
SPAIN
Tel: + 34 946 741 085
Fax: +34 946 744 829
Mail: info@quimunsa.com

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

COEX PIPETTES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIXIE 402 mg spot-on solution for very large dogs
Fipronil

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4.02 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch{number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blisters (plastic supports (PVC-PE) covered by a polyester / polyethylene complex)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIXIE 402 mg spot-on solution for very large dogs
Fipronil

2. NAME OF THE MARKETING AUTHORISATION HOLDER

QUIMUNSA

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch: {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.