

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
Carton boxes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIPTRON 268 mg spot-on solution for Large Dogs
Fipronil

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each pipette of 2.68 ml contains: 268 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

5. TARGET SPECIES

Dogs 20-40 kg

6. INDICATION(S)

The treatment and prevention of infestations by fleas (*Ctenocephalides* spp.) and ticks (*Rhipicephalus* spp, *Ixodes* spp,) and as part of the treatment strategy for Flea Allergy Dermatitis, where has been previously diagnosed by a veterinary surgeon.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot on use.

One pipette of 2.68 ml per dog weighing over 20kg and up to 40kg bodyweight

Method of administration

Hold upright. Tap the narrow part of the pipette to ensure the contents are within the main body of the pipette.

Break back the snap-off top from the spot-on pipette along the scored line. Part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze gently at one or two spots to empty its contents onto the skin.

Care should be taken to avoid excessive wetting of the hair with the product since this will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

In the absence of safety studies, the minimum treatment interval is 4 weeks.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Do not use in rabbits, as adverse reactions and even death could occur.

10. EXPIRY DATE

<EXP {month/year}>

11. SPECIAL STORAGE CONDITIONS

Store below 30°C
Store in the original package

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

Dispose of waste material in accordance with local requirements.
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

Química de Munguía S.A.
Derio Bidea, 51
48100 Munguia (Vizcaya)
Spain

16. MARKETING AUTHORISATION NUMBER(S)**17. MANUFACTURER’S BATCH NUMBER**

<Batch> {number}

MINIMUM PARTICULARS TO APPEAR ON PIPETTES

Coex pipettes

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Fipronil

2. NAME OF THE MARKETING AUTHORISATION HOLDER

QUIMUNSA

3. EXPIRY DATE

Impressed: {month/year}>

4. BATCH NUMBER

Impressed: {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.