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

2. STATEMENT OF ACTIVE SUBSTANCES

Each pipette (2.68 ml) contains:

Fipronil 268 mg

3. PACKAGE SIZE

Package sizes:

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

4. TARGET SPECIES

Dogs 20-40 kg

5. INDICATIONS

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

6. ROUTES OF ADMINISTRATION

Spot-on use.

Read the package leaflet before use.

7. WITHDRAWAL PERIODS

Not applicable

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package

Store below 30ºC

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

Quimica de Munguia S.A. (Quimunsa)

14. MARKETING AUTHORISATION NUMBER

Vm 45883/4005

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS { Blisters (plastic supports (PVC-PE) covered by a polyester / polyethylene complex)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diptron 268 mg spot-on solution for large dogs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Fipronil…..268 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

<Exp. {mm/yyyy}>

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {COEX PIPETTES}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diptron 268 mg spot-on solution for large dogs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Fipronil…..268 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

<Exp. {mm/yyyy}>

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Diptron 67 mg spot-on solution for small dogs

Diptron 134 mg spot-on solution for medium dogs

Diptron 268 mg spot-on solution for large dogs

Diptron 402 mg spot-on solution for very large dogs

Fipronil

2. Composition

Each pipette contains:

Active substance:

DIPTRON spot-on solution for dogs	Volume of unit dose (ml)	Fipronil (mg)
small dogs – 2-10 kg	0.67	67
medium dogs – 10-20 kg	1.34	134
large dogs – 20-40 kg	2.68	268
very large dogs – 40-60 kg	4.02	402

Excipients:

DIPTRON spot-on solution for dogs	Butylhydroxyanisole (E320) (mg)	Butylhydroxytouene (E321) (mg)
small dogs – 2-10 kg	0.13	0.07
medium dogs – 10-20 kg	0.27	0.13
large dogs – 20-40 kg	0.54	0.27
very large dogs – 40-60 kg	0.80	0.40

3. Target species

Dogs

4. Indications for use

Treatment of existing flea (*Ctenocephalides felis*) infestations and prevention of re-infestation with fleas through insecticidal effect for up to 5 weeks. 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 can be used as part of the strategy in the treatment of flea allergy dermatitis (FAD), where this has been previously diagnosed by a veterinarian.

5. Contraindications

In the absence of available data, the product should not be used in puppies less than 8 weeks of age (and / or weighing less than 2 kg).

Do not use on sick (systemic diseases, fever…) or convalescent animals.

Do not use in rabbits, as adverse reactions and even death could occur.

This product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:

For external use only. Do not apply the product on wounds or damaged skin.

Avoid contact with the animal's eyes. In case of accidental eye contact immediately and thoroughly flush the eyes with water.

Animals should be weighed accurately prior to treatment (See section 5).

It is important to make sure that the product is applied to an area where the animal cannot lick it off, and to make sure that animals do not lick each other following treatment

The potential toxicity of the product for puppies less than 8 weeks of age in contact with a treated bitch is not documented. Special care should be taken in this case.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

This product may cause neurotoxicity. Keep stored pipettes in the original packaging until ready to use. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately.

People with a known hypersensitivity to fipronil or any of the excipients should avoid contact with the veterinary medicinal product.

This product can cause mucous membrane and eye irritation. Therefore, contact of the product with mouth and eyes should be avoided. In case of accidental ocular exposure or irritation of the eyes during administration, these should be rinsed immediately and thoroughly with plain water. If eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

Avoid contents coming into contact with the fingers. In case of dermal exposure, wash immediately with soap and water.

Wash hands after use.

Do not smoke, drink or eat during application.

Treated animals should not be handled, and children should not be allowed to play with them until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals should not be allowed to sleep with owners, especially children.

Special precautions for the protection of the environment:

Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in watercourses for 2 days after application.

Pregnancy and lactation:

Laboratory studies in rats have not shown evidence of teratogenic or fetotoxic effects.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian."

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with other flea products which are applied directly onto the animal.

Major incompatibilities:

Not applicable

7. Adverse events

Target species: Dogs

Rare (1 to 10 animals / 10,000 animals treated):	Transient cutaneous reactions at the application site (skin discoloration, local alopecia, pruritus, erythema, capillary bleeding) and general pruritus or alopecia.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs.

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

Route of administration – Spot-on use.

Dosage:

1 pipette of 0.67 ml per dog weighing over 2 kg and up to 10 kg bodyweight

1 pipette of 1.34 ml per dog weighing over 10 kg and up to 20 kg bodyweight

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

1 pipette of 4.02 ml per dog weighing over 40 kg and up to 60 kg bodyweight

For dogs over 60 kg use two pipettes of 2.68 ml.

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.

9. Advice on correct administration

Do not use the product if you notice visible signs of deterioration.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 30ºC

Keep the blister in the outer carton

Do not use this veterinary medicinal product after the expiry date which is stated on the blister after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

The veterinary medicinal product should not enter water courses as fipronil may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

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 national collection systems applicable to the veterinary medicinal product concerned.

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 not subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 45883/4003

Vm 45883/4004

Vm 45883/4005

Vm 45883/4006

Package sizes:

Carton box containing 1,2,3,4,5,6,7,8,10,12,24,30,60,90,120 or 150 pipettes

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

Quimica de Munguia S.A. (Quimunsa)
Derio Bidea, 51
48100 Munguía- Vizcaya
SPAIN
Tel. +34 946 741 085

complaints@quimunsa.com

info@quimunsa.com

Manufacturer responsible for batch release:

QUIMICA DE MUNGUÍA S.A.
Derio Bidea, 51
48100 Munguía- Vizcaya
SPAIN
AB7 SANTE
Chemin des Monges, Deume, 32450
Montgiscard
France

17. Other information

NFA-
VPS

Gavin Hall
Approved: 27 March 2025