PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON BOXES}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diptron 50 mg Spot-On solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each pipette of 0.5 ml contains:

Fipronil 50 mg

3. PACKAGE SIZE

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

4. TARGET SPECIES

Cats

5. INDICATIONS

Treatment and prevention of flea infestations (*Ctenocephalides felis*). Fleas present on the animal at the time of product application will be killed within 48 hours. The product has persistent insecticidal efficacy lasting for 4 weeks against *Ctenocephalides felis* fleas.

Treatment and prevention of tick infestations (*Rhipicephalus turanicus*). Ticks present on the animal at the time of product application will be killed within 48 hours. The product has persistent acaricidal efficacy for 4 weeks against *Rhipicephalus turanicus* ticks.

6. ROUTES OF ADMINISTRATION

Spot-on use.

1 pipette of 0.50 ml per cat.

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.

7. WITHDRAWAL PERIODS

Not applicable

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

QUIMUNSA

14. MARKETING AUTHORISATION NUMBERS

Vm 45883/4000

15. BATCH NUMBER

Batch {number}

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diptron 50 mg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each pipette of 0.5 ml contains:

Fipronil 50 mg

3. BATCH NUMBER

Batch {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET
Diptron 50 mg spot-on solution for cats

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diptron 50 mg Spot-on Solution for Cats

2. Composition

Each pipette of 0.5 ml contains:

Active substance:
Fipronil…….50 mg
Excipients:
Butylhydroxyanisole (E320)……...0.10 mg
Butylhydroxytoluene (E321)……. 0.05 mg

Clear, colourless to yellow solution.

3. Target species

Cats

4. Indications for use

'Treatment and prevention of flea infestations (Ctenocephalides felis). Fleas present on the animal at the time of product application will be killed within 48 hours. The product has persistent insecticidal efficacy lasting for 4 weeks against Ctenocephalides felis fleas.
Treatment and prevention of tick infestations (Rhipicephalus turanicus). Ticks present on the animal at the time of product application will be killed within 48 hours. The product has persistent acaricidal efficacy for 4 weeks against Rhipicephalus turanicus ticks.'

5. Contraindications

Do not use on kittens less than 9 weeks old and/or weighing less than 1 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.

Do not apply on wounds or damaged skin.

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

6. Special warnings

During the period of expected efficacy, ticks will be killed and fall off the host within 48 hours of infestation, usually without having had a blood meal. However,

the attachment of single ticks may occur after treatment and therefore the transmission of infectious diseases by ticks cannot be excluded. Once dead, ticks will often drop off the animal, but any remaining ticks can be removed carefully.

'The impact of bathing/immersion in water or shampooing on product effectiveness has not been investigated and therefore cannot be recommended, especially within 2 days of product application.

For optimum control of flea problems in a multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.

Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in case of massive infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

Special precautions for use in animals

For external use only.

Avoid contact with the animal’s eyes.
Animals should be weighed accurately prior to treatment.

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.

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

This veterinary medicinal 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 veterinary medicinal product can cause mucous membrane and eye irritation. Therefore, contact between the veterinary medicinal product and the mouth or 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 until the application site is dry, 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.

Pregnancy and lactation:

Laboratory studies in rats have not produced any 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.

Overdose (symptoms, emergency procedures, antidotes):
No adverse effects were observed in target animal safety studies in cats and kittens of 9 weeks of age and weighing about 1 kg where the animals received the recommended dose, three (3X) and five (5X) times the recommended dose. The risk of experiencing adverse effects may however increase with overdosing (see section 7.). Itching may occur following treatment.

7. Adverse events

Cats:

Rare (1 to 10 animals / 10,000 animals treated):	Excessive salivation / drooling
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Transient cutaneous reactions at the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia. 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 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

Spot-on use.1 pipette of 0.5 mL per cat

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

None

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Shelf-life after first opening the immediate packaging: immediate use.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton 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.

This veterinary medicinal product should not enter water courses as fipronil may be dangerous for fish and other aquatic organisms.

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. These measures should help 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 45883/4000

Package sizes:

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

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:

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

Tel. +34 946 741 085

info@quimunsa.com

Manufacturer responsible for batch release:

QUIMICA DE MUNGUÍA S.A.

Derio Bidea, 51

48100 Munguía- Vizcaya

SPAIN

17. Other information

NFA- VPS

Gavin Hall
Approved: 10 July 2025