PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imidaflea 250 mg Spot-on solution for Large Dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Imidacloprid 250 mg

3. PACKAGE SIZE

1 x 2.5 ml

2 x 2.5 ml

3 x 2.5 ml

4 x 2.5 ml

6 x 2.5 ml

4. TARGET SPECIES

Dogs

5. INDICATIONS

For the prevention and treatment of flea infestations and for the treatment of biting lice *(Trichodectes canis)* on dogs from 10 kg to less than 25 kg body weight.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks.

6. ROUTES OF ADMINISTRATION

Spot-on use.

7. WITHDRAWAL PERIODS

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.

Store pipettes in the original packaging until ready to use.

This product can cause mucous membrane, skin and eye irritation.

Therefore, contact of the product with mouth, skin and eyes should be avoided.

This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling).

People with a known hypersensitivity (allergy) to insecticides or alcohol should avoid contact with the product.

Do not smoke, drink or eat during application.

If contact with the skin occurs, wash hands with soap and water.

If the product gets into eyes, the eyes should be thoroughly rinsed with clean water. If skin or eye irritation persists, or the product is accidentally swallowed, seek medical advice.

Do not stroke, groom or play with treated animals 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 are not allowed to sleep with owners, especially children.

Dispose of used pipettes immediately.

Wash hands after 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

Chanelle Pharmaceuticals Manufacturing Ltd

14. MARKETING AUTHORISATION NUMBERS

Vm 08749/5206
Vm 08749/3169

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Sachet}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imidaflea 250 mg Spot-on solution for Large Dogs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Imidacloprid 250 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Pieptte}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imidaflea Spot-on

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Imidacloprid 250 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

Imidaflea 250 mg Spot-on solution for Large Dogs

2. Composition

Each 1 ml contains:

Active substance:

Imidacloprid 250 mg

Excipients:

Butylhydroxytoluene (E 321) 2.5 mg

3. Target species

Dogs.

4. Indications for use

For the prevention and treatment of flea infestations and for the treatment of biting lice *(Trichodectes canis)* on dogs from 10 kg to less than 25 kg body weight.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks.

5. Contraindications

Do not treat unweaned puppies of less than 8 weeks of age.

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

6. Special warnings

Special warnings:

If signs of disease persist or appear, consult a veterinary surgeon.

This product is for topical use and should not be administered orally.

Care should be taken to avoid the contents of the pipette coming into contact with the eyes or mouth of the recipient animal.

Do not allow recently treated animals to groom each other.

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

This product can cause mucous membrane, skin and eye irritation.

Therefore, contact of the product with mouth, skin and eyes should be avoided.

This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling).

People with a known hypersensitivity (allergy) to insecticides or alcohol should avoid contact with the product.

Do not smoke, drink or eat during application.

If contact with the skin occurs, wash hands with soap and water.

If the product gets into eyes, the eyes should be thoroughly rinsed with clean water. If skin or eye irritation persists, or the product is accidentally swallowed, seek medical advice.

Do not stroke, groom or play with treated animals 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 are not allowed to sleep with owners, especially children.

Dispose of used pipettes immediately.

Wash hands after use.

Special precautions for the protection of the environment:

Imidacloprid is toxic to aquatic organisms. To avoid adverse effects on aquatic organisms, treated dogs should not be allowed to enter surface water for 48 hours after treatment.

Pregnancy and lactation:

No primary embryotoxic, teratogenic or reproductive toxic effects have been observed during the studies with imidacloprid on rats and rabbits. Studies on pregnant and lactating bitches together with their offspring are limited.

Evidence so far suggests that no adverse effects are to be expected in these animals. Consult your veterinary surgeon before using in pregnant or nursing animals.

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.

Overdose:

No adverse clinical signs were produced by either individual doses of up to 200 mg/kg body weight (five to eight times the therapeutic dose), daily treatments at 100 mg/kg body weight for five consecutive days or weekly treatments at five times the maximum dose rate for eight consecutive weeks.

In rare cases of overdose or licking of treated fur, nervous system disorders (such as twitching, tremors, ataxia, mydriasis, miosis, lethargy) can occur.

Poisoning following inadvertent oral uptake in animals is unlikely. In this event, treatment should be symptomatic under veterinary medical attention. There is no known specific antidote but administration of activated charcoal may be beneficial.

Major incompatibilities:

None known.

7. Adverse events

Dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Agitation Hypersalivation[1] Disorientation, Neurological signs (e.g. Depression, Incoordination, Tremor) Application site reaction (e.g. Hair loss, Itching, Reddening of the skin, Skin lesion)

[1] May occur if the dog licks the application site immediately after treatment due to the bitter taste. This is not a sign of intoxication and disappears within some minutes without treatment.

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

This product is for external use only and should not be administered orally. Animals should be weighed accurately prior to treatment.

Dosage and Treatment Schedule

Dog (kg body weight)	Product	Number of Pipettes	Imidaflea (mg/kg body weight)
From 10 kg to less than 25 kg	Imidaflea 250 for Dogs	1 x 2.5 ml	minimum of 10

Re-infestation from emergence of new fleas in the environment may continue to occur for six weeks or longer after treatment is initiated. More than one treatment may therefore be required, depending on the level of fleas in the environment. To aid

in environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developing stages is recommended.

The product remains effective if the animal becomes wet, for example after swimming or exposure to heavy rain.

However, in cases of frequent swimming or bathing re-treatment may become necessary, depending on the presence of fleas in the environment. In these cases do not re-treat more frequently than once weekly.

In cases of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

Method of administration:

Apply only to undamaged skin. Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Snap back the tip. With the dog in the standing position, part the coat between the shoulder blades until the skin is visible.

Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot.

Temporary changes to the coat (clumped/greasy hair) may be noted at the application site.

Correct application will minimise the opportunity for the animal to lick the product.

9. Advice on correct administration

Discard any opened pipettes.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label 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 Imidacloprid 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 applicable national collection systems. These measures should help to protect the environment.

Do not contaminate ponds, waterways or ditches with the product or empty containers.

13. Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 08749/5206
Vm 08749/3169

Box with 1, 2, 3, 4, 6 pipettes in individual foil sachets.

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:

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
H62 FH90
Ireland

Contact details to report suspected adverse reactions:

EU Pharmaceuticals Ltd
37 Geraldine Road
London SW18 2NR
UK
Telephone: +353 (0) 91 841788
vetpharmacoviggroup@chanellegroup.ie

17. Other information

AVM-GSL

Gavin Hall
Approved: 06 November 2025