PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imidaflea 80 mg Spot-on solution for Large Cats and Large Pet Rabbits

2. STATEMENT OF ACTIVE SUBSTANCES

Imidacloprid 80 mg

3. PACKAGE SIZE

1 x 0.8 ml

2 x 0.8 ml

3 x 0.8 ml

4 x 0.8 ml

6 x 0.8 ml

4. TARGET SPECIES

Cats and pet rabbits

5. INDICATIONS

Prevention and treatment of flea *(Ctenocephalides felis)* infestations in cats of 4 kg body weight and greater.

Treatment of flea infestations in rabbits of 4 kg body weight and greater.

Fleas are killed within one day following treatment. One treatment prevents further flea infestation for three to four weeks on cats and up to one week on pet rabbits.

6. ROUTES OF ADMINISTRATION

Spot-on use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Do not use on rabbits intended for human consumption

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 08749/5204
Vm 08749/3167

15. BATCH NUMBER

Lot {number}

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imidaflea 80 mg Spot-on solution for Large Cats and Large Pet Rabbits

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Imidacloprid 80 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imidaflea Spot-on

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Imidacloprid 80 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 80 mg Spot-on Solution for Large Cats and Large Pet Rabbits

2. Composition

Each 1 ml contains:

Active substance:

Imidacloprid 80 mg

Excipients:

Butylhydroxytoluene (E 321) 0.8 mg

3. Target species

Cats and pet rabbits.

4. Indications for use

Prevention and treatment of flea *(Ctenocephalides felis)* infestations in cats of 4 kg body weight and greater.

Treatment of flea infestations in rabbits of 4 kg body weight and greater.

Fleas are killed within one day following treatment. One treatment prevents further flea infestation for three to four weeks on cats and up to one week on pet rabbits.

5. Contraindications

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

Do not use on pet rabbits of less than 10 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:

This product is for topical use and should not be administered orally.
Apply only to undamaged skin
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 for each target species:

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

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 reduction in environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developing stages is recommended. In order to reduce further the environmental challenge, it is recommended that all cats and rabbits in the household are treated. The product remains effective if the animal becomes wet, for example after exposure to heavy rain. However, retreatment may become necessary, depending on the presence of fleas in the environment. In these cases do not treat more frequently than once weekly.

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.

Other Precautions:

The solvent in this product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

Pregnancy and lactation:

No reproductive toxic effects have been observed in rats and no primary embryotoxic or teratogenic toxic effects have been observed during the studies on rats and rabbits. Studies on pregnant and lactating queens and does 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:

In cats, no adverse clinical signs were produced using doses of five times the therapeutic level weekly for eight consecutive weeks.

In rabbits, no adverse clinical signs were seen using doses of up to 45 mg/kg body weight (4 times the therapeutic level) weekly for 4 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 in cats.

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

Cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Agitation Diarrhoea[1] , Hypersalivation[2] , Vomiting[1] Neurological signs (e.g. Depression, Incoordination, Tremor) Application site reaction (e.g. Hair loss, Itching, Reddening of the skin, Skin lesion)

[1] May occur after oral ingestion.
[2] May occur if the cat 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.

Rabbits:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Agitation Diarrhoea[1] , Hypersalivation[2] Application site reaction (e.g. Hair loss, Itching, Reddening of the skin, Skin lesion)

[1] May occur after oral ingestion.
[2] May occur if the cat 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.

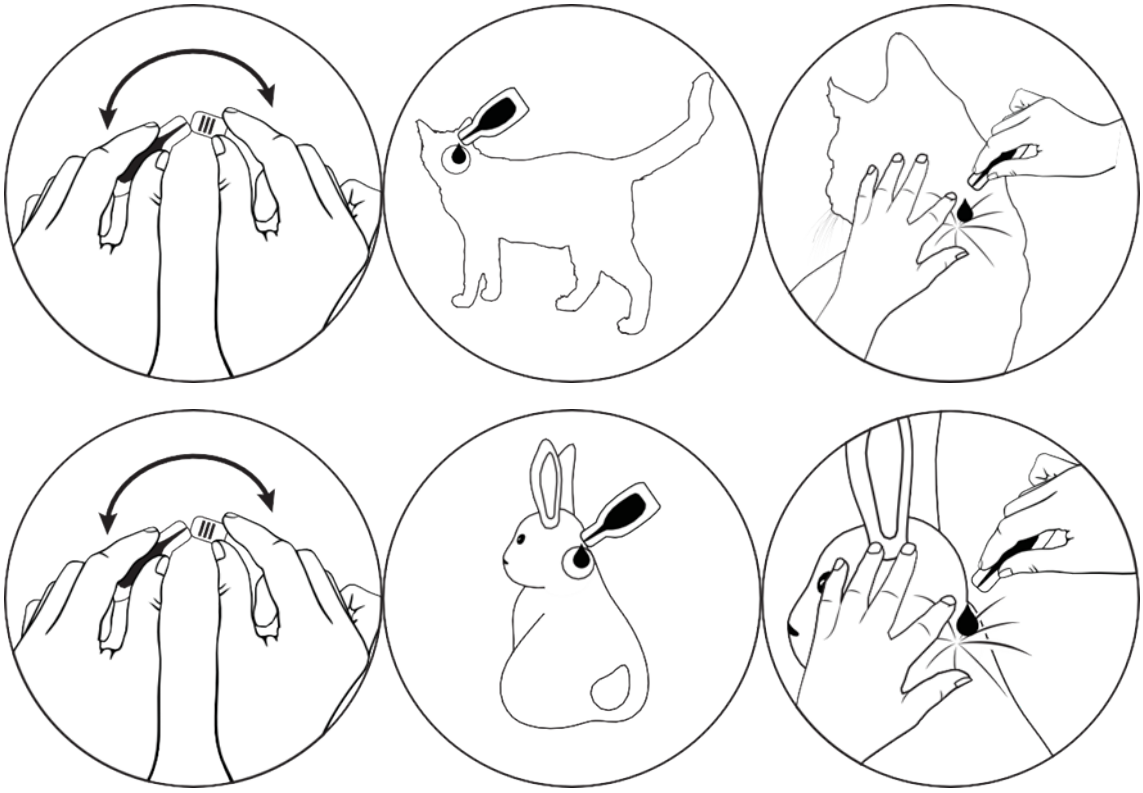
Dosage and Treatment Schedule

Cat/Rabbit (kg body weight)	Product	Number of Pipettes	Imidaflea (mg/kg body weight)
4 kg and greater	Imidaflea 80 for Large Cats and Large Pet Rabbits	1 x 0.8 ml	minimum of 10

Method of administration:

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. Part the hair on the animal's neck at the base of the skull 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. 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

Do not use on rabbits intended for human consumption.

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 08749/5204
Vm 08749/3167

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