

PARTICULARS TO APPEAR ON THE OUTER PACKAGE { CARDBOARD BOX }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imoxat 80 mg + 8 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.8 ml pipette contains 80 mg imidacloprid and 8 mg moxidectin

3. PACKAGE SIZE

1 pipette
3 pipettes

4. TARGET SPECIES

For large cats weighing between 4 kg and 8 kg.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Spot-on use.

For external use only.
Read the package leaflet before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package in order to protect from light and moisture.
Do not store above 25°C.

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

Chanelle Pharmaceuticals Manufacturing Ltd

14. MARKETING AUTHORISATION NUMBERS

Vm 08749/5029

15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS { SACHET (PET/Alu/NYLON/LDPE)}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imoxat spot-on solution
(> 4–8 kg) 🐾

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

80 mg imidacloprid and 8 mg moxidectin

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS { PIPETTE (PP/COC/EVOH/PP)}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imoxat



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

(> 4–8 kg)

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

Imoxat 40 mg + 4 mg spot-on solution for small cats and ferrets

Imoxat 80 mg + 8 mg spot-on solution for large cats

2. Composition

Each unit dose pipette contains:

	Unit dose	Imidacloprid	Moxidectin
Imoxat for small cats (≤ 4 kg) and ferrets	0.4 ml	40 mg	4 mg
Imoxat for large cats (> 4 –8 kg)	0.8 ml	80 mg	8 mg

Excipients: benzyl alcohol, 1 mg/ml butylhydroxytoluene (E321).

Colourless to yellow solution.

3. Target species

Cats, ferrets.

4. Indications for use

For cats suffering from, or at risk from, mixed parasitic infections:

- the treatment and prevention of flea infestation (*Ctenocephalides felis*),
- the treatment of ear mite infestation (*Otodectes cynotis*),
- the treatment of notoedric mange (*Notoedres cati*),
- the treatment of the lungworm *Eucoleus aerophilus* (syn. *Capillaria aerophila*) (adults),
- the prevention of lungworm disease (L3/L4 larvae of *Aelurostrongylus abstrusus*),
- the treatment of the lungworm *Aelurostrongylus abstrusus* (adults),
- the treatment of the eye worm *Thelazia callipaeda* (adults),
- the prevention of heartworm disease (L3 and L4 larvae of *Dirofilaria immitis*),
- the treatment of infections with gastrointestinal nematodes (L4 larvae, immature adults and adults of *Toxocara cati* and *Ancylostoma tubaeforme*).

The veterinary medicinal product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

For ferrets suffering from, or at risk from, mixed parasitic infections:

- the treatment and prevention of flea infestation (*Ctenocephalides felis*),
- the prevention of heartworm disease (L3 and L4 larvae of *Dirofilaria immitis*).

5. Contraindications

Do not use in kittens under 9 weeks of age.

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

For ferrets: do not use Imoxat for large cats (0.8 ml) or Imoxat for dogs (any size).

For dogs, the corresponding “Imoxat for dog” product, which contains 100 mg/ml imidacloprid and 25 mg/ml moxidectin, must be used.

Do not use on canaries.

6. Special warnings

The veterinary medicinal product’s efficacy has not been tested in ferrets weighing over 2 kg and therefore the duration of effect might be shorter in these animals.

Brief contact of the animal with water on one or two occasions between monthly treatments is unlikely to significantly reduce the efficacy of the product. However, frequent shampooing or immersion of the animal in water after treatment may reduce the efficacy of the product.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class. Therefore, the use of this veterinary medicinal product should be based on the assessment of each individual case and on local epidemiological information about the current susceptibility of the target species in order to limit the possibility of a future selection for resistance. The use of the veterinary medicinal product should be based on the confirmed diagnosis of mixed infection (or risk of infection, where prevention applies) at the same time (see also sections 4 and 8).

Special precautions for safe use in the target species:

Treatment of cats weighing less than 1 kg and ferrets weighing less than 0.8 kg should be based on a benefit-risk assessment.

There is limited experience on the use of the veterinary medicinal product in sick and debilitated animals, thus the veterinary medicinal product should only be used based on a benefit-risk assessment for these animals.

Do not apply in the mouth, in the eyes or the ears of the animal.

Care should be taken that the veterinary medicinal product is not ingested by animals and does not come into contact with the eyes or mouth of the recipient and/or other

animals. Consider carefully the correct application method described in section 9, especially that the veterinary medicinal product should be applied to the site specified in order to minimise the risk for the animal to lick the veterinary medicinal product. Do not allow recently treated animals to groom each other. Do not allow treated animals to come into contact with untreated animals until the application site is dry.

In case of accidental oral uptake, symptomatic treatment should be administered. There is no known specific antidote. The use of activated charcoal may be beneficial.

It is recommended that cats and ferrets living in, or travelling to, areas endemic for heartworm are treated monthly with the veterinary medicinal product to protect them from heartworm disease.

Whilst the accuracy of diagnosis of heartworm infection is limited, it is recommended that attempts be made to check the heartworm status of any cat and ferret aged over 6 months, prior to beginning of prophylactic treatment, as use of the veterinary medicinal product on cats or ferrets which have adult heartworm may cause serious adverse effects, including death. If adult heartworm infection is diagnosed, the infection should be treated in accordance with current scientific knowledge.

In certain individual cats *Notoedres cati* infestation may be severe. In these severe cases concomitant supportive treatment is necessary as treatment with the veterinary medicinal product alone may not be sufficient to prevent death of the animal.

Imidacloprid is toxic for birds, especially canaries.

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

Avoid contact with skin, eyes or mouth.

Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

After application do not stroke or groom animals until the application site is dry.

In case of accidental spillage onto skin, wash off immediately with soap and water.

People with known hypersensitivity to benzyl alcohol, imidacloprid or moxidectin should administer the veterinary medicinal product with caution. In very rare cases the veterinary medicinal product may cause skin sensitisation or transient skin reactions (for example numbness, irritation or burning/tingling sensation).

In very rare cases the veterinary medicinal product may cause respiratory irritation in sensitive individuals.

If the veterinary medicinal product accidentally gets into eyes, they should be thoroughly flushed with water.

If skin or eye symptoms persist, or the veterinary medicinal product is accidentally swallowed, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in the target species. Therefore, the use of the product is not recommended in animals intended for breeding or during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

During treatment with the veterinary medicinal product no other antiparasitic macrocyclic lactone should be administered.

No interactions between the veterinary medicinal product and routinely used veterinary medicinal products or medical or surgical procedures have been observed.

Overdose:

Up to 10 times the recommended dose was tolerated in cats with no evidence of adverse effects or undesirable clinical signs.

The veterinary medicinal product was administered to kittens at up to 5 times the recommended dose, every 2 weeks for 6 treatments, and there were no serious safety concerns. Transient mydriasis, salivation, vomiting and transient rapid respiration were observed.

After accidental oral ingestion or overdose, neurological signs (most of which are transient) such as ataxia, generalised tremors, ocular signs (dilated pupils, little pupillary reflex, nystagmus), abnormal respiration, salivation and vomiting may occur in very rare cases.

The veterinary medicinal product was administered to ferrets at 5 times the recommended dose, every 2 weeks for 4 treatments, and there was no evidence of adverse effects or undesirable clinical signs.

Other precautions:

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

7. Adverse events

{Cats and ferrets}

Rare (1 to 10 animals / 10000 animals treated):	Application site greasy fur ¹ Vomiting ¹ Hypersensitivity reactions (local) Erythema ¹
Very rare (<1 animal / 10000 animals treated, including isolated reports):	Behavioural disorder (e.g. agitation) ² Hypersalivation ^{3,4} Neurological signs ³ Pruritus ⁵ Lethargy ² and inappetence ²

1: These signs disappear without further treatment.

2: Transiently noted and related to sensation at application site.

3: If the animal licks the application site after treatment, (most of which are transient).

4: The veterinary medicinal product tastes bitter. Salivation may occasionally occur if the animal licks the application site immediately after treatment. This is not a sign of intoxication and disappears within some minutes without treatment. Correct application will minimise licking of the application site.

5: Transient in Cats

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 the local representative of 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

Method of administration

Spot-on use.

For external use only.

To prevent licking, apply topically to the skin restricting the area of application to the animal's neck at the base of the skull.

Dosage schedule for cats:

The recommended minimum doses are 10 mg/kg bodyweight imidacloprid and 1.0 mg/kg bodyweight moxidectin, equivalent to 0.1 ml/kg bodyweight of the veterinary medicinal product.

The treatment schedule should be based on individual veterinary diagnosis and on the local epidemiological situation.

Weight of cat [kg]	Pipette size to be used	Volume [ml]	Imidacloprid [mg/kg bw]	Moxidectin [mg/kg bw]
≤ 4 kg	Imoxat for small cats and ferrets	0.4	minimum of 10	minimum of 1
> 4–8 kg	Imoxat for large cats	0.8	10–20	1–2
> 8 kg	the appropriate combination of pipettes			

Flea treatment and prevention (*Ctenocephalides felis*)

One treatment prevents future flea infestation for 4 weeks. Existing pupae in the environment may emerge for 6 weeks or longer after treatment is initiated, depending upon climatic conditions. Therefore, it may be necessary to combine animal treatment with environmental treatments aimed at breaking the flea life cycle in the surroundings. This can result in a more rapid reduction in the household flea population. The veterinary medicinal product should be administered at monthly intervals when used as part of a treatment strategy for flea allergy dermatitis.

Treatment of ear mite infestation (*Otodectes cynotis*)

A single dose of the veterinary medicinal product should be administered. A further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment. Do not apply directly to the ear canal.

Treatment of notoedric mange (*Notoedres cati*)

A single dose of the veterinary medicinal product should be administered.

Treatment of the lungworm *Eucoleus aerophilus* (syn. *Capillaria aerophila*) (adults)

A single dose of the veterinary medicinal product should be administered.

Prevention of *Aelurostrongylus abstrusus*

The veterinary medicinal product should be administered monthly.

Treatment of *Aelurostrongylus abstrusus*

The veterinary medicinal product should be administered monthly for three consecutive months.

Treatment of the eye worm *Thelazia callipaeda* (adults)

A single dose of the veterinary medicinal product should be administered.

Heartworm prevention (*Dirofilaria immitis*)

Cats in areas endemic for heartworm, or those which have travelled to endemic areas, may be infected with adult heartworms. Therefore prior to treatment with the veterinary medicinal product, the advice provided in section “SPECIAL WARNING(S)” should be considered.

For prevention of heartworm disease, the veterinary medicinal product must be applied at regular monthly intervals during the time of the year when mosquitoes (the intermediate hosts which carry and transmit heartworm larvae) are present. The veterinary medicinal product may be administered throughout the year. The first dose may be given after first possible exposure to mosquitoes, but not more than one month after this exposure. Treatment should continue at regular monthly intervals until 1 month after the last exposure to mosquitoes. To establish a treatment routine, it is recommended that the same day or date be used each month. When replacing another heartworm preventative product in a heartworm prevention programme, the first treatment with the veterinary medicinal product must be given within 1 month of the last dose of the former medication.

In non-endemic areas there should be no risk of cats having heartworm. Therefore, they can be treated without special precautions.

Roundworm and hookworm treatment (*Toxocara cati* and *Ancylostoma tubaeforme*)

In areas endemic for heartworm, monthly treatment may significantly reduce the risk of re-infection caused by the respective roundworms and hookworms. In areas non-endemic for heartworm, the veterinary medicinal product can be used as part of a seasonal prevention programme against fleas and gastrointestinal nematodes.

Dosage schedule for ferrets:

One pipette of Imoxat spot-on solution for small cats (0.4 ml) should be administered per animal.

Do not exceed the recommended dose.

The treatment schedule should be based on the local epidemiological situation.

Flea treatment and prevention (*Ctenocephalides felis*)

One treatment prevents future flea infestation for 3 weeks. Under heavy flea pressure it may be necessary to repeat administration after 2 weeks.

Heartworm prevention (*Dirofilaria immitis*)

Ferrets in areas endemic for heartworm, or those which have travelled to endemic areas, may be infected with adult heartworms. Therefore prior to treatment with the veterinary medicinal product, the advice provided in section “SPECIAL WARNING(S)” should be considered.

For prevention of heartworm disease, the veterinary medicinal product must be applied at regular monthly intervals during the time of the year when mosquitoes (the intermediate hosts which carry and transmit heartworm larvae) are present. The

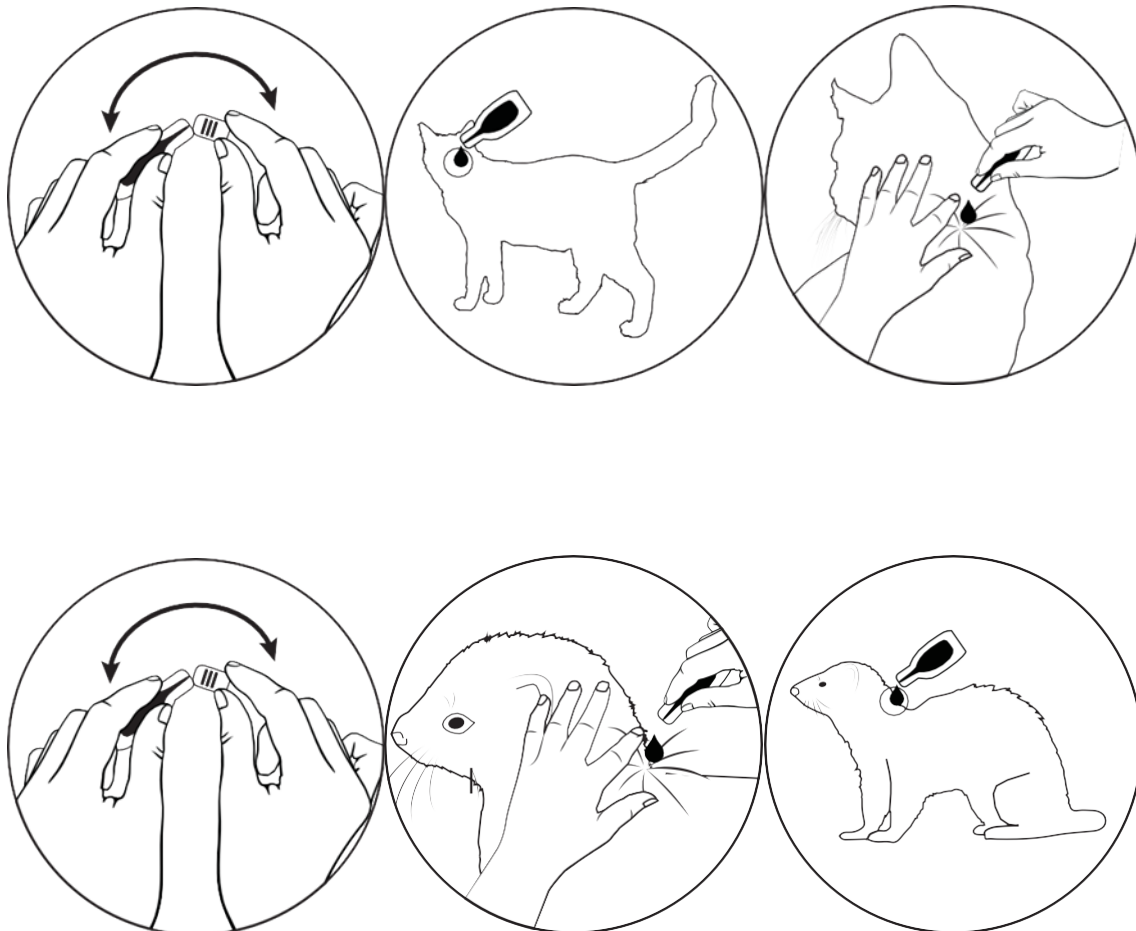
veterinary medicinal product may be administered throughout the year. The first dose may be given after first possible exposure to mosquitoes, but not more than one month after this exposure. Treatment should continue at regular monthly intervals until 1 month after the last exposure to mosquitoes.

In non-endemic areas there should be no risk of ferrets having heartworm. Therefore they can be treated without special precautions.

9. Advice on correct administration

Remove one pipette from the package. Tap the narrow part of the tube to ensure the contents are within the main body of the tube. Snap back the tip of the pipette to enable the contents to be expelled.

Part the fur 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 firmly several times to empty its contents directly onto the skin. Application at the base of the skull will minimise the opportunity for the animal to lick the veterinary medicinal product. Apply only to undamaged skin.



10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original package in order to protect from light and moisture.

Do not store above 25°C.

Do not use this veterinary medicinal product after the expiry date stated on the label and carton. 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 and moxidectin 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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 08749/5028

Vm 08749/5029

Pack sizes: 0.4 ml and 0.8 ml per pipette.

Each cardboard box contains 1 or 3 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 and contact details to report suspected adverse reactions:

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
H62 FH90
Ireland
Telephone: +353 (0)91 841788
vetpharmacoviggroup@chanellegroup.ie

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Imidacloprid is effective against larval flea stages and adult fleas. Flea larvae in the pet's surroundings are killed after contact with a pet treated with the product.

The veterinary medicinal product has a persistent action and protects cats for 4 weeks after a single application against reinfection with *Dirofilaria immitis*.

Studies evaluating the pharmacokinetic behaviour of moxidectin after multiple applications have indicated that steady state serum levels are achieved following approximately 4 consecutive monthly treatments in cats.

Environmental properties

Moxidectin has been classified as persistent, bioaccumulative and toxic in the environment.

Gavin Hall
Approved: 10 December 2025