PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 0.8 ml pipette contains 80 mg imidacloprid and 8 mg moxidectin
Butylhydroxytoluene 0.8 mg/ml
Benzyl alcohol 0.8 ml

3. PACKAGE SIZE

1 pipette
2 pipettes
3 pipettes
4 pipettes
6 pipettes
24 pipettes

4. TARGET SPECIES

For large cats weighing between 4 kg and 8 kg.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Spot-on use.

7. WITHDRAWAL PERIOD(S)

8. EXPIRY DATE

EXP {month/year}

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 NUMBER

Vm 08749/3011

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

POM-V (Veterinary medicinal product subject to prescription)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SACHET (PET/Alu/NYLON/LDPE)
Ridamax for large cats

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ridamax

(> 4–8 kg)

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

80 mg /8 mg
Imidacloprid/moxidectin

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {month/year}

5. ROUTE(S) OF ADMINISTRATION

Spot-on use

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

PIPETTE (PP/COC/EVOH/PP)
Ridamax for large cats

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ridamax
(> 4–8 kg)

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {month/year}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:
Ridamax 40 mg + 4 mg spot-on solution for small cats and ferrets
Ridamax 80 mg + 8 mg spot-on solution for large cats

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ridamax 40 mg + 4 mg spot-on solution for small cats and ferrets
Ridamax 80 mg + 8 mg spot-on solution for large cats

2. COMPOSITION

Each unit dose pipette contains:

	Unit dose	Imidacloprid	Moxidectin	Butyl-hydroxytoluene	Benzyl alcohol
Ridamax for small cats (≤ 4 kg) and ferrets	0.4 ml	40 mg	4 mg	4 mg	0.4 ml
Ridamax for large cats (> 4–8 kg)	0.8 ml	80 mg	8 mg	8 mg	0.8 ml

A clear 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 Ridamax for large cats (0.8 ml) or Ridamax for dogs (any size).

For dogs, the corresponding “Ridamax 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

Special warnings for each target species:
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.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection/infestation based on its epidemiological features, for each individual animal. 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 use in animals:
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:
People with a known hypersensitivity to benzyl alcohol, imidacloprid or moxidectin should administer this 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 this product may cause respiratory irritation in sensitive individuals.
In order to prevent children getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.
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. This may be ensured by treating animals in the evening. Do not allow recently treated animals to sleep with owners, especially children.
In case of accidental spillage onto skin, wash off immediately with soap and water.
If the product accidentally gets into eyes, they should be thoroughly flushed with water.
If skin or eye symptoms persist, or the product is accidentally swallowed, seek medical advice immediately and show the package leaflet or label to the physician.

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.

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 (symptoms, emergency procedures, antidotes):
The following information is derived from studies investigating an alternative veterinary medicinal product (of equivalent composition).
Up to 10 times the recommended dose was tolerated in cats with no evidence of adverse effects or undesirable clinical signs.

Following administration to kittens at up to 5 times the recommended dose, every 2 weeks for 6 treatments, 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.

Following administration to ferrets at 5 times the recommended dose, every 2 weeks for 4 treatments, there was no evidence of adverse effects or undesirable clinical signs.

There is no known specific antidote.

Incompatibilities:
Not applicable

7. ADVERSE EVENTS

Cats and Ferrets

Rare (1 to 10 animals / 10,000 animals treated):	Application site greasy fur[1] Erythema[1] Vomiting[1] Hypersensitivity reaction
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Neurological signs[2] Lethargy[3], Inappetence[3] Agitation[3]
'Undetermined frequency (cannot be estimated from the available data):	Pruritus[3,4]

[1]These signs disappear without further treatment.
[2] These signs are mostly transient and can occur if the animal licks the application site after treatment.
[3]Transient.
[4]In cats.

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.

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 local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system https://www.gov.uk/report-veterinary-medicine-problem

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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.

Underdosing could result in ineffective use and may favour resistance development. To ensure a correct dosage, body weight should be determined as accurately as possible. For infestations/infections with the indicated parasites, the need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

Weight of cat [kg]	Pipette size to be used	Volume [ml]	Imidacloprid [mg/kg bw]	Moxidectin [mg/kg bw]
≤ 4 kg	Ridamax for small cats and ferrets	0.4	minimum of 10	minimum of 1
> 4–8 kg	Ridamax 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 Ridamax spot-on solution for small cats (0.4 ml) should be administered per animal.
Do not exceed the recommended dose.

Underdosing could result in ineffective use and may favour resistance development. To ensure a correct dosage, body weight should be determined as accurately as possible. For infestations/infections with the indicated parasites, the need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

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.

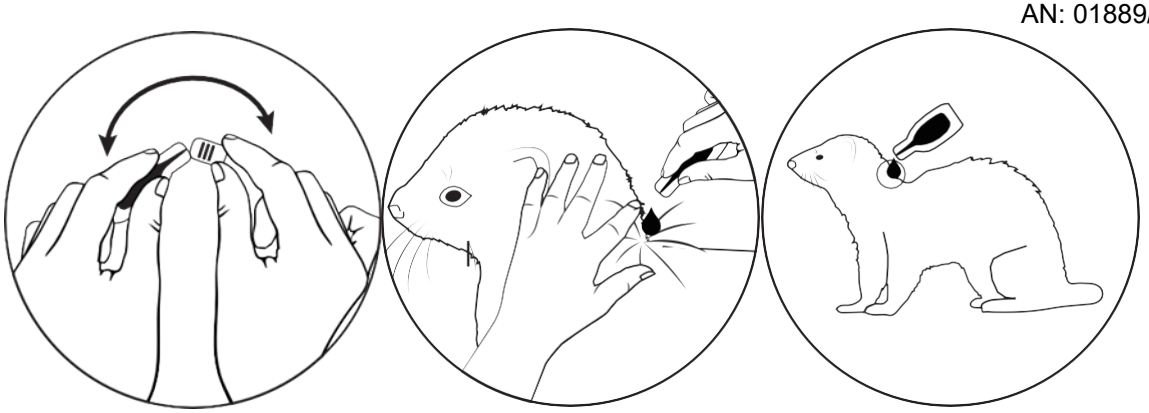
Heartworm prevention (Dirofilaria immitis)
Ferrets in areas endemic for heartworm, or those which have travelled to endemic areas, may be infected with adult heartworms. Therefore prior to treatment with the veterinary medicinal product, the advice provided in section "SPECIAL WARNING(S)" should be considered.

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 PERIOD(S)

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.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
The veterinary medicinal product should not enter water courses as this may be dangerous for fish and other aquatic organisms. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 08749/5046 (GB) (0.4 ml)
Vm 08749/3010 (NI) (0.4 ml)
Vm 08749/5047 (GB) (0.8 ml)
Vm 08749/3011 (NI) (0.8 ml).

Pack sizes: 0.4 ml and 0.8 ml per pipette.

Each pipette is packed into an individual sachet.
Carton containing 1 individual sachet.
Carton containing 2 individual sachets.
Carton containing 3 individual sachets.
Carton containing 4 individual sachets.
Carton containing 6 individual sachets.
Carton containing 24 individual sachets.
Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

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
Ireland

17. OTHER INFORMATION

POM-V (Veterinary medicinal product subject to prescription)

For animal treatment only.

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.

Approved 17 January 2024