

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ridamax 400 mg + 100 mg spot-on solution for extra-large dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 4 ml pipette contains 400 mg imidacloprid, 100 mg moxidectin, 4 mg butylhydroxytoluene and 4 ml of benzyl alcohol.

3. PACKAGE SIZE

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

4. TARGET SPECIES

For extra-large dogs weighing between 25 kg and 40 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 08749/3015

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 extra-large dogs

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ridamax

(> 25–40 kg)



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

400 mg/100 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 extra-large dogs

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ridamax
(> 25–40 kg)



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

Each 4 ml pipette contains:
400 mg imidacloprid and 100 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 + 10 mg spot-on solution for small dogs
Ridamax 100 mg + 25 mg spot-on solution for medium dogs
Ridamax 250 mg + 62.5 mg spot-on solution for large dogs
Ridamax 400 mg + 100 mg spot-on solution for extra-large dogs

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ridamax 40 mg + 10 mg spot-on solution for small dogs
Ridamax 100 mg + 25 mg spot-on solution for medium dogs
Ridamax 250 mg + 62.5 mg spot-on solution for large dogs
Ridamax 400 mg + 100 mg spot-on solution for extra-large dogs

2. COMPOSITION

Each unit dose pipette contains:

	Unit dose	Imidacloprid	Moxidectin	Butylhydroxytoluene	Benzyl alcohol
Ridamax for small dogs (≤ 4 kg)	0.4 ml	40 mg	10 mg	0.4 mg	0.4 ml
Ridamax for medium dogs (> 4 – 10 kg)	1.0 ml	100 mg	25 mg	1.0 mg	1.0 ml
Ridamax for large dogs (> 10 – 25 kg)	2.5 ml	250 mg	62.5 mg	2.5 mg	2.5 ml
Ridamax for extra-large dogs (> 25 – 40 kg)	4.0 ml	400 mg	100 mg	4.0 mg	4.0 ml

A clear colourless to yellow solution.

3. TARGET SPECIES

Dogs

4. INDICATIONS FOR USE

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

- the treatment and prevention of flea infestation (*Ctenocephalides felis*),
- the treatment of biting lice (*Trichodectes canis*),
- the treatment of ear mite infestation (*Otodectes cynotis*), sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*), demodicosis (caused by *Demodex canis*),
- the prevention of heartworm disease (L3 and L4 larvae of *Dirofilaria immitis*),
- the treatment of circulating microfilariae (*Dirofilaria immitis*),
- the treatment of cutaneous dirofilariosis (adult stages of *Dirofilaria repens*)
- the prevention of cutaneous dirofilariosis (L3 larvae of *Dirofilaria repens*),

- the reduction of circulating microfilariae (*Dirofilaria repens*),
- the prevention of angiostrongylosis (L4 larvae and immature adults of *Angiostrongylus vasorum*),
- the treatment of *Angiostrongylus vasorum* and *Crenosoma vulpis*,
- the prevention of spirocercosis (*Spirocerca lupi*),
- the treatment of *Eucoleus* (syn. *Capillaria*) *boehmi* (adults),
- the treatment of the eye worm *Thelazia callipaeda* (adults),
- the treatment of infections with gastrointestinal nematodes (L4 larvae, immature adults and adults of *Toxocara canis*, *Ancylostoma caninum* and *Uncinaria stenocephala*, adults of *Toxascaris leonina* and *Trichuris vulpis*).

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

5. CONTRAINDICATIONS

Do not use in puppies under 7 weeks of age.

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

Do not use in dogs classified as Class 4 for heartworm disease as the safety of the product has not been evaluated in this animal group.

For cats, the corresponding “Ridamax for cat” product, which contains 100 mg/ml imidacloprid and 10 mg/ml moxidectin, must be used.

For ferrets: do not use Ridamax for dogs. Only “Ridamax for small cats and ferrets” (0.4 ml) must be used.

Do not use on canaries.

6. SPECIAL WARNING(S)

Special warnings for each target species:

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 veterinary medicinal 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).

Efficacy against adult *Dirofilaria repens* has not been tested under field conditions.

Special precautions for use in animals:

Treatment of animals weighing less than 1 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.

When the veterinary medicinal product is applied in 3 to 4 separate spots, specific care should be taken to prevent the animal licking the application sites.

This veterinary medicinal product contains moxidectin (a macrocyclic lactone), therefore special care should be taken with Collie or Old English Sheep dogs and related breeds or crossbreeds, to correctly administer the veterinary medicinal product as described under the section "ADVICE ON CORRECT ADMINISTRATION"; in particular, oral uptake by Collie or Old English Sheep dogs and related breeds or crossbreeds should be prevented.

The veterinary medicinal product should not enter water courses as this may be dangerous for fish and other aquatic organism: moxidectin is highly toxic to aquatic organisms. Dogs should not be allowed to swim in surface waters for 4 days after treatment.

The safety of an alternative veterinary medicinal product (of equivalent composition) has only been evaluated in dogs classified as either Class 1 or 2 for heartworm disease in laboratory studies and in a few Class 3 dogs in a field study. Therefore the use of the veterinary medicinal product in dogs with obvious or severe symptoms of the disease should be based on a careful benefit-risk assessment by the treating veterinarian.

Although experimental overdose studies have shown that an alternative veterinary medicinal product (of equivalent composition) may be safely administered to dogs infected with adult heartworms, it has no therapeutic efficacy against adult *Dirofilaria immitis*. It is therefore recommended that all dogs 6 months of age or more, living in areas endemic for heartworm, should be tested for existing adult heartworm infection before being treated with the veterinary medicinal product. At the discretion of the veterinarian, infected dogs should be treated with an adulticide to remove adult heartworms. The safety of the veterinary medicinal product has not been evaluated when administered on the same day as an adulticide.

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 this product may cause skin sensitisation or transient skin reactions (for example numbness, irritation or burning/tingling sensation).

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.

In very rare cases this product may cause respiratory irritation in sensitive individuals. 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 the label to the physician.

Special precautions for the protection of the environment:

Treated dogs should not be allowed to enter surface water for 48 hours after treatment to avoid adverse effects on aquatic organisms.

Other precautions

The solvent in this 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 are expected between the veterinary medicinal product and routinely used veterinary medicinal products or medical or surgical procedures.

Safety of the veterinary medicinal product when administered on the same day as an adulticide to remove adult heartworms has not been evaluated.

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 adult dogs with no evidence of adverse effects or undesirable clinical signs. Five times the recommended minimum dose applied at weekly intervals for 17 weeks was investigated in dogs aged over 6 months and tolerated with no evidence of adverse effects or undesirable clinical signs.

Following administration to puppies 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.

Ivermectin-sensitive Collie dogs tolerated up to 5 times the recommended dose repeated at monthly intervals without any adverse effects, but the safety of application at weekly intervals has not been investigated in ivermectin-sensitive Collie dogs. When 40 % of the unit dose was given orally, severe neurological signs were observed. Oral administration of 10 % of the recommended dose produced no adverse effects.

Dogs infected with adult heartworms tolerated up to 5 times the recommended dose, every 2 weeks for 3 treatments, without any adverse effects.

There is no known specific antidote.

Incompatibilities:

Not applicable

For animal treatment only

Keep out of the sight and reach of children.

7. ADVERSE REACTIONS

Dogs

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

¹These signs are transient and disappear without further treatment.

²These signs are mostly transient and can occur if the animal licks the application site after treatment.

³Transient.

Heartworm positive dogs with microfilaraemia:

Common (1 to 10 animals / 100 animals treated):	Respiratory tract disorders (Cough, Tachypnoea, Dyspnoea) ¹ Digestive tract disorders (Vomiting, Diarrhoea) Inappetence Lethargy
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¹May require prompt veterinary treatment.

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.

Apply topically to the skin between the shoulder blades.

Dosage schedule

The recommended minimum doses are 10 mg/kg bodyweight imidacloprid and 2.5 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 dog [kg]	Pipette size to be used	Volume [ml]	Imidacloprid [mg/kg bw]	Moxidectin [mg/kg bw]
≤ 4 kg	Ridamax for small dogs	0.4	minimum of 10	minimum of 2.5
> 4–10 kg	Ridamax for medium dogs	1.0	10–25	2.5–6.25
> 10–25 kg	Ridamax for large dogs	2.5	10–25	2.5–6.25
> 25–40 kg	Ridamax for extra-large dogs	4.0	10–16	2.5–4
> 40 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 biting lice (Trichodectes canis)

A single dose should be administered. A further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

Treatment of ear mite infestation (Otodectes cynotis)

A single dose of the veterinary medicinal product should be administered. Loose debris should be gently removed from the external ear canal at each treatment. 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 sarcoptic mange (caused by Sarcoptes scabiei var. canis)

A single dose should be administered twice 4 weeks apart.

Treatment of demodicosis (caused by Demodex canis)

The administration of a single dose every 4 weeks for 2 to 4 months is efficacious against *Demodex canis* and leads to a marked improvement of clinical signs particularly in mild to moderate cases. Especially severe cases may require more prolonged and more frequent treatment. To achieve the best possible response in these severe cases, at the discretion of the veterinarian, the veterinary medicinal product can be applied once a week and for a prolonged time. In all cases it is essential that the treatment should be continued until skin scrapings are negative on at least 2 consecutive monthly occasions. Treatment should be stopped in dogs that show no improvement or do not respond in mite count after 2 months treatment. Alternative treatment should be administered. Seek the advice of your veterinarian.

As demodicosis is a multi-factorial disease, where possible, it is advisable to also treat any underlying disease appropriately.

Prevention of heartworm disease (D. immitis)

Dogs 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 *D. immitis*) 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 dogs having heartworm. Therefore they can be treated without special precautions.

Prevention of cutaneous dirofilariosis (skinworm) (D. repens)

For prevention of cutaneous dirofilariosis, 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 *D. repens* larvae) are present. The veterinary medicinal product may be administered throughout the year or at least 1 month before the first expected exposure to mosquitoes. 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.

Treatment of microfilariae (D. immitis)

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

Treatment of cutaneous dirofilariosis (skin worm) (adult stages of Dirofilaria repens)

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

Reduction of microfilariae (skin worm) (D. repens)

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

Treatment and prevention of Angiostrongylus vasorum

A single dose should be administered. A further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment. In endemic areas regular monthly application will prevent angiostrongylosis and patent infection with *Angiostrongylus vasorum*.

Treatment of Crenosoma vulpis

A single dose should be administered.

Prevention of spirocercosis (Spirocerca lupi):

The veterinary medicinal product should be administered monthly.

Treatment of Eucoleus (syn. Capillaria) boehmi (adults)

The veterinary medicinal product should be administered monthly for two consecutive months. It is advisable to prevent auto-coprophagia between the two treatments in order to prevent possible reinfection.

Treatment of the eye worm Thelazia callipaeda (adults)

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

Roundworm, hookworm and whipworm treatment (*Toxocara canis*, *Ancylostoma caninum*, *Uncinaria stenocephala*, *Toxascaris leonina* and *Trichuris vulpis*).

In areas endemic for heartworm, monthly treatment may significantly reduce the risk of re-infection caused by the respective round-, hook- and whipworms. 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.

Studies investigating an alternative veterinary medicinal product (of equivalent composition) have shown that monthly treatment of dogs will prevent infections caused by *Uncinaria stenocephala*.

9. ADVICE ON CORRECT ADMINISTRATION

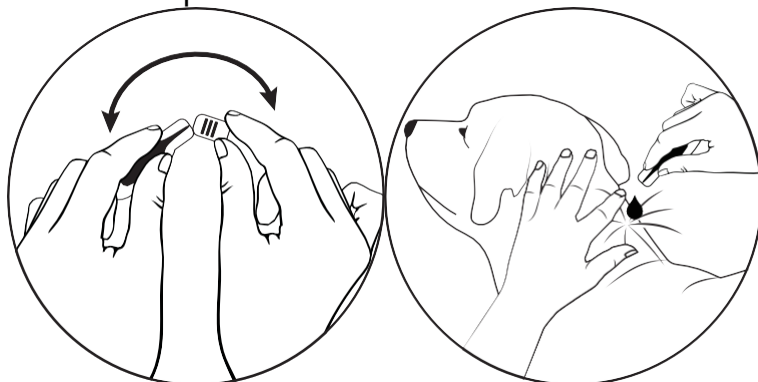
Remove one pipette from the package. Tap the narrow part of the tube to ensure the contents are within the main body of the tube. Snap back the tip of the pipette to enable the contents to be expelled.

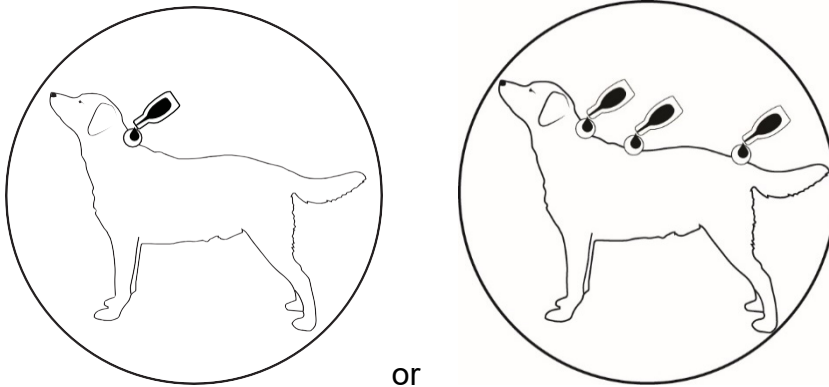
For dogs up to 25 kg:

With the dog in a standing position, part the coat between the shoulder blades until the skin is visible. Wherever possible apply to undamaged skin. Place the tip of the pipette on the skin and squeeze the pipette firmly several times to empty its contents directly onto the skin.

For dogs of more than 25 kg:

For easy application the dog should be standing. The entire contents of the pipette should be applied evenly as 3 or 4 spots along the top of the back, from between the shoulders to the base of the tail. At each spot, part the coat until the skin is visible. Wherever possible apply to undamaged skin. Place the tip of the pipette on the skin and gently squeeze the pipette to expel a portion of its contents directly onto the skin. Do not apply an excessive amount of solution at any one spot, as that could cause some of the product to run down the animal's side.





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 08749/3012 (0.4 ml)

Vm 08749/3013 (1.0 ml)

Vm 08749/3014 (2.5 ml)

Vm 08749/3015 (4.0 ml)

Pack sizes: 0.4 ml 1.0 ml, 2.5 ml and 4.0 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. 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

Ireland

Telephone: +353 (0)91 841788

vetpharmacoviggroup@chanellegroup.ie

17. OTHER INFORMATION

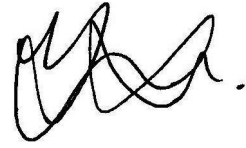
POM-V (Veterinary medicinal product subject to prescription)

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 dogs for 4 weeks after a single application against re-infection with the following parasites: *Dirofilaria immitis*, *Dirofilaria repens*, *Angiostrongylus vasorum*.

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 dogs.

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 23 April 2024