SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ridamax for dogs contains 100 mg/ml imidacloprid, 25 mg/ml moxidectin, benzyl alcohol 4 ml and butylhydroxytoluene 1 mg/ml

Each unit dose (pipette) of 4 ml delivers:

Active substances:
Imidacloprid 400 mg
Moxidectin 100 mg

Excipients:
Benzyl alcohol 4 ml
Butylhydroxytoluene (E321) 4.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.

Colourless to yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

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).

4.3 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.

4.4 Special warnings for each target species

Please refer to section 4.5.

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 4.2 and 4.9).

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

4.5 Special precautions for use

Special precautions for use in animals

The 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 risk-benefit 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 4.9, 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 (see section 4.9), 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 Collies, Old English Sheepdogs and related breeds or crossbreeds, to correctly administer the veterinary medicinal product as described under section 4.9; 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 it has harmful effects on aquatic organisms: 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 overdosage 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 effect 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 the veterinary medicinal 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 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.

4.6 Adverse reactions (frequency and seriousness)

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 eythema[1] Neurological signs[2] Lethargy[3], Inappetence[3] Agitation[3]
'Undetermined frequency (cannot be estimated from the available data):	Pruritus[3]

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

[3]Transient.

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

[1]May 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also section 16 of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

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.

4.8 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.

4.9 Amount(s) to be administered and administration route

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 4.5 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*, T*oxascaris 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 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.*

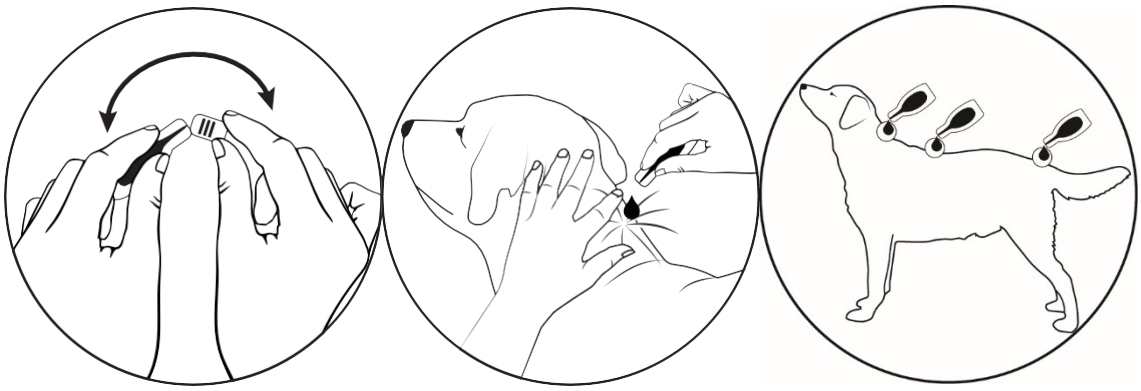
Method of administration

Spot-on use.
For external use only.

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

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.



4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic products, insecticides and repellents, macrocyclic lactones, milbemycins. ATCvet code: QP54AB52.

5.1 Pharmacodynamic properties

Imidacloprid, 1-(6-Chloro-3-pyridylmethyl)-N-nitro-imidazolidin-2-ylideneamine is an ectoparasiticide belonging to the chloronicotinyl group of compounds. Chemically, it is more accurately described as a chloronicotinyl nitroguanidine. Imidacloprid is active 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. Imidacloprid has a high affinity for the nicotinergic acetylcholine receptors in the post-synaptic region of the central nervous system (CNS) of the flea. The ensuing inhibition of cholinergic transmission in insects results in paralysis and death. Due to the weak nature of the interaction with mammalian nicotinergic receptors and the postulated poor penetration through the blood-brain barrier in mammals, it has virtually no effect on the mammalian CNS. Imidacloprid has minimal pharmacological activity in mammals.

Moxidectin, 23-(O-methyloxime)-F28249 alpha is a second-generation macrocyclic lactone of the milbemycin family. It is a parasiticide which is active against many internal and external parasites. Moxidectin is active against larval stages (L3, L4) of *Dirofilaria immitis.* It is also active against gastrointestinal nematodes. Moxidectin interacts with GABA and glutamate-gated chloride channels. This leads to opening of the chloride channels on the postsynaptic junction, the inflow of chloride ions and

induction of an irreversible resting state. The result is flaccid paralysis of affected parasites, followed by their death and/or expulsion.
The veterinary medicinal product has a persistent action and protects dogs for 4 weeks after a single application against reinfection with the following parasites: *Dirofilaria immitis*, *Dirofilaria repens*, *Angiostrongylus vasorum.*

5.2 Pharmacokinetic particulars

After topical administration of the veterinary medicinal product, imidacloprid is rapidly distributed over the animal's skin within one day of application. It can be found on the body surface throughout the treatment interval. Moxidectin is absorbed through the skin, reaching maximum plasma concentrations approximately 4 to 9 days after treatment in dogs. Following absorption from the skin, moxidectin is distributed systemically throughout the body tissues but due to its lipophilicity it is concentrated mainly in the fat. It is slowly eliminated from the plasma as manifested by detectable moxidectin concentrations in plasma throughout the treatment interval of one month. The T ½ in dogs is about 28.4 days.
Studies evaluating the pharmacokinetic behaviour of moxidectin after multiple applications (using an alternative veterinary medicinal product of equivalent composition) have indicated that steady state serum levels are achieved following approximately 4 consecutive monthly treatments in dogs.

Environmental properties

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

See sections 4.5. and 6.6.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Butylhydroxytoluene (E321)
Propylene carbonate

6.2 Major incompatibilities

Not applicable

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Pipette: a white pipette composed of a heat-formed shell composed of (polypropylene (PP)/cyclic olefin copolymer (COC)/ethylene vinyl alcohol EVOH)/polypropylene(PP) with a snap-off cap.
Sachet: polyethylene (PET)/aluminium foil/nylon/low density polyethylene (LDPE)

Pack size: 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products 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.

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 08749/5051

9. DATE OF FIRST AUTHORISATION

23 April 2024

10. DATE OF REVISION OF THE TEXT

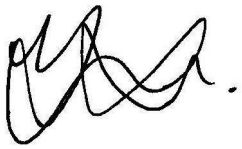
April 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.



Approved: 23 April 2024