ANNEX III

LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prinocate 250 mg/62.5 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2.5 ml pipette contains: 250 mg imidacloprid, 62.5 mg moxidectin.

3. PACKAGE SIZE

1x 2.5 ml
3 x 2.5 ml
4 x 2.5 ml
6 x 2.5 ml
24 x 2.5 ml
48 x 2.5 ml

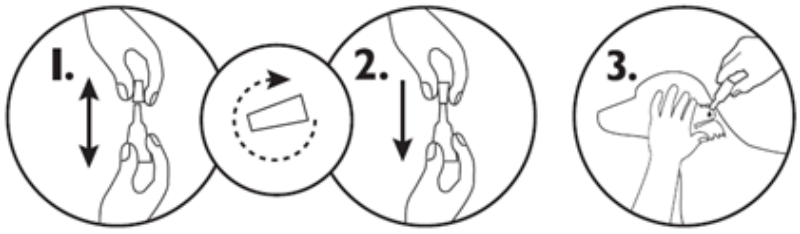
4. TARGET SPECIES

Large dogs (>10-25 kg).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Spot-on 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.

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

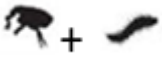
KRKA, d.d., Novo mesto

14. MARKETING AUTHORISATION NUMBER

Vm 01656/4185

15. BATCH NUMBER

Lot {number}

 *Ctenocephalides felis*

Trichodectes canis

Otodectes cynotis

Sarcoptes scabiei var. *canis*

Demodex canis

Dirofilaria immitis

Dirofilaria immitis microfilariae

Dirofilaria repens

Angiostrongylus vasorum

Crenosoma vulpis

Spirocerca lupi

Eucoleus (syn. Capillaria) boehmi

Thelazia callipaeda

Toxocara canis, Toxascaris leonina

Ancylostoma caninum, Uncinaria stenocephala

Trichuris vulpis

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BAG

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prinocate

>10-25 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

imidacloprid/moxidectin

250 mg/62.5 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PIPETTE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prinocate

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

>10-25 kg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Active substances, excipients:

	Volume [ml]	Imidacloprid [mg]	Moxidectin [mg]	Butylhydroxytoluene (E 321) [mg]	Benzyl alcohol (E 1519) [mg]
Prinocate 40 mg/10 mg spot-on solution for small dogs	0.4	40	10	0.4	323
Prinocate 100 mg/25 mg spot-on solution for medium dogs	1	100	25	1	807
Prinocate 250 mg/62.5 mg spot-on solution for large dogs	2.5	250	62.5	2.5	2018
Prinocate 400 mg/100 mg spot-on solution for extra-large dogs	4	400	100	4	3229

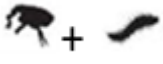
Clear, slightly yellow to yellow or to brownish yellow solution.

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*),

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),
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 cases 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 veterinary medicinal product has not been evaluated in this animal group.
For cats, the corresponding veterinary medicinal product (0.4 or 0.8 ml), which contains 100 mg/ml imidacloprid and 10 mg/ml moxidectin, must be used.
For ferrets: Do not use the veterinary medicinal product for dogs. Only the veterinary medicinal product for small cats and ferrets (0.4 ml) should be used.
Do not use on canaries.

6. Special warnings

Special warnings:
Please refer to sub-section “Special precautions for safe use in the 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 veterinary medicinal product. However, frequent shampooing or immersion of the animal in water after treatment may reduce the efficacy of the veterinary medicinal 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 “Indications for use” and “Dosage for each species,

routes and method of administration”). Efficacy against adult *Dirofilaria repens* has not been tested under field conditions.

Special precautions for safe use in the target species:
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 benefit-risk assessment for these animals.
Care should be taken that the contents of the pipette or the applied dose does not come into contact with the eyes or mouth of the recipient and/or other animals. Do not allow recently treated animals to groom each other. When the veterinary medicinal product is applied in 3 to 4 separate spots (see section “Advice on correct administration”), specific care should be taken to prevent the animal licking the application sites.
The veterinary medicinal product should only be applied to undamaged skin.
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 section “Advice on correct administration”; in particular, oral uptake by the recipient and/or other animals in close contact should be prevented.
The safety of the veterinary medicinal product 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 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 the veterinary medicinal product 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 combination of imidacloprid and moxidectin 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:
In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.
Do not ingest. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
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.
Avoid contact with skin, eyes or mouth.
In case of accidental spillage onto skin, wash off immediately with soap and water.

Wash hands thoroughly after use.
If skin or eye symptoms persist, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not eat, drink or smoke during application.
Treated animals should not be handled especially by children until the application site is dry. Therefore, it is recommended to apply the veterinary medicinal product in the evening. Recently treated animals should not be allowed to sleep in the same bed as their owner, especially children.

Special precautions for the protection of the environment:
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.

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. Laboratory studies with either imidacloprid or moxidectin in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

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 imidacloprid/moxidectin combination and routinely used veterinary medicinal products or medical or surgical procedures have been observed. Safety of the veterinary medicinal product when administered on the same day as an adulticide to remove adult heartworms has not been evaluated.

Overdose:
Up to 10 times the recommended dose of the combination of imidacloprid and moxidectin 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.
The combination of imidacloprid and moxidectin was administered to puppies 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.
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. 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.

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):
Diarrhoea[1], Vomiting[1] Cough[1], Dyspnoea (abnormal breathing)[1], Tachypnoea (hyperventilation)[1] Inappetence[1], Lethargy[1]
Rare (1 to 10 animals / 10,000 animals treated):
Vomiting[2] Application site greasy fur[2], Application site erythema (redness)[2], Hypersensitivity reaction[3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Behavioural disorders (e.g. agitation)[4] Inappetence[4], Lethargy[4] Neurological signs[5]
Undetermined frequency (cannot be estimated from the available data):
Pruritus (itching)[6] Salivation[7]

[1]These signs are common in heartworm positive dogs with microfilaraemia. In a case of severe respiratory signs (cough, dyspnoea, tachypnoea) prompt veterinary treatment may be required.
[2]Thesesigns disappear without further treatment.
[3]Local.
[4]Transiently noted and related to sensation at application site.
[5]Most occur transiently and if animal licks the application site after treatment (see “Overdose”).

[6]Transient.
[7]Occurs if the animal licks the application site immediately after treatment. This is not a sign of intoxication and disappears within 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 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:
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

Spot-on use. For external use only.

Apply topically to the skin between the shoulder blades.

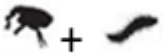
Dosage schedule:

The recommended minimum doses are 10 mg/kg bodyweight imidacloprid and 2.5 mg/kg bodyweight moxidectin, equivalent to 0.1 ml/kg bodyweight.

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

Administer in accordance with the following table:

Dogs [kg]	Pipette size to be used	Volume [ml]	Imidacloprid [mg/kg b.w.]	Moxidectin [mg/kg b.w.]
≤4	imidacloprid/moxidectin 40 mg/10 mg spot-on solution for small dogs	0.4	minimum of 10	minimum of 2.5
>4-10	imidacloprid/moxidectin 100 mg/25 mg spot-on solution for medium dogs	1	10-25	2.5-6.25
>10-25	imidacloprid/moxidectin 250 mg/62.5 mg spot-on solution for large dogs	2.5	10-25	2.5-6.25
>25-40	imidacloprid/moxidectin 400 mg/100 mg spot-on solution for extra-large dogs	4	10-16	2.5-4
>40	the appropriate combination of pipettes to provide the recommended dose (the minimum recommended dose is 0.1 ml veterinary medicinal product/kg bodyweight)			

Flea treatment and prevention (*Ctenocephalides felis*) 

One treatment prevents future flea infestation for 4 weeks. Pre-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 treatment with the veterinary medicinal product 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*) and cutaneous dirofilariosis (skinworm) (*D. repens*)

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 warnings” should be considered. For prevention of heartworm disease and 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. immitis* and *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. When replacing another heartworm preventative veterinary medicinal product in a heartworm prevention programme, the first treatment with this 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.

<u>Treatment of microfilariae (*D. immitis*)</u>

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

<u>Treatment of cutaneous dirofilariosis (skin worm) (adult stages of *Dirofilaria repens*)</u>

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

<u>Reduction of microfilariae (skin worm) (*D. repens*)</u>

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

<u>Treatment and prevention of *Angiostrongylus vasorum*</u>

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 applications will prevent angiostrongylosis and patent infection with *Angiostrongylus vasorum*.

<u>Treatment of *Crenosoma vulpis*</u>

A single dose should be administered.

<u>Prevention of spirocercosis (*Spirocerca lupi*)</u>

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.

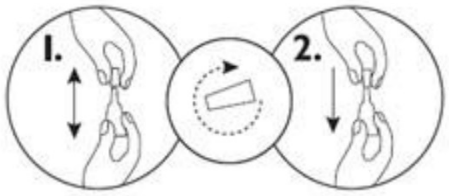
Roundworm, hookworm and whipworm treatment (*Toxocara canis, Ancylostoma caninum, Uncinaria stenocephala, Toxascaris leonina* and *Trichuris vulpis*).

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 have shown that monthly treatment of dogs will prevent infections caused by *Uncinaria stenocephala.*

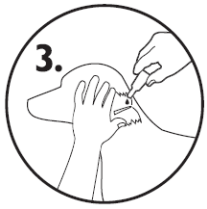
9. Advice on correct administration

1. Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off.
2. Turn the cap around and place the other end of cap back on pipette. Push and twist the cap to break seal, and then remove the cap from the pipette.



For dogs up to 25 kg:

3. With the dog standing still, part the coat between the shoulder blades until the skin is visible. The veterinary medicinal product should only be applied to undamaged skin. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



For dogs of more than 25 kg:

3. 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. The veterinary medicinal product should only be applied to undamaged skin. Place the tip of the pipette on the skin and gently squeeze the pipette to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot, as that could cause some of the veterinary medicinal product to run down the animal's side.

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. This veterinary medicinal product does not require any special temperature storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

This veterinary medicinal product should not enter water courses as imidacloprid 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 01656/4183
Vm 01656/4184
Vm 01656/4185
Vm 01656/4186

Pack sizes:
Cardboard box containing 1, 3, 4, 6, 24 or 48 pipettes.
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:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Local representatives and contact details to report suspected adverse reactions:
KRKA UK Ltd
United Kingdom
Tel: 02071 646 156
info.uk@krka.biz

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

17. Other information

POM-V	Veterinary medicinal product subject to prescription

Gavin Hall

Approved: 19 May 2026