

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prinocate 80 mg/8 mg spot-on solution for large cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.8 ml pipette contains:

Active substances:

Imidacloprid	80 mg
Moxidectin	8 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzyl Alcohol (E 1519)	658 mg
Propylene Carbonate	
Butylhydroxytoluene (E 321)	0.8 mg
Trolamine	

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

3. CLINICAL INFORMATION

3.1 Target species

Large cats (>4-8 kg).

3.2 Indications for use for each target species

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).

3.3 Contraindications

Do not use in kittens under 9 weeks of age.

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

Do not use this veterinary medicinal product for large cats (0.8 ml) or the veterinary medicinal product for dogs (any size) in ferrets.

For dogs, the corresponding veterinary medicinal product, which contains 100 mg/ml imidacloprid and 25 mg/ml moxidectin, must be used.

Do not use on canaries.

3.4 Special warnings

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 3.2 and 3.9).

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

The veterinary medicinal product should only be applied to undamaged skin.

Care should be taken that the content 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.

It is recommended that cats 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 aged over 6 months, before beginning prophylactic treatment, as use of the veterinary medicinal product on cats which have adult heartworms 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:

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:

Not applicable.

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.

3.6 Adverse events

Cats:

Rare (1 to 10 animals / 10,000 animals treated):	Vomiting ¹ Application site greasy fur ¹ , Application site erythema ¹ , Hypersensitivity reaction. ²
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Behavioural disorders (e.g. agitation, lethargy) ³ Inappetence ³ Neurological signs ⁴
Undetermined frequency (cannot be estimated from the available data):	Pruritus ⁵ Hypersalivation ⁶

¹These signs disappear without further treatment.

²Local.

³Transiently noted and related to sensation at application site.

⁴Most occur transiently and if animal licks the application site after treatment (see section 3.10).

⁵Transient.

⁶Occurs 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 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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 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 between the veterinary medicinal product and routinely used veterinary medicinal products or medical or surgical procedures have been observed.

3.9 Administration routes and dosage

For external use only (spot-on use).

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

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

Administer in accordance with the following table:

Cats [kg]	Pipette size to be used	Volume [ml]	Imidacloprid [mg/kg b.w.]	Moxidectin [mg/kg b.w.]
>4-8	imidacloprid/moxidectin 80 mg/8 mg spot-on solution for large cats	0.8	10-20	1-2
>8	the appropriate combination of pipettes 0.8 ml and 0.4 ml (intended for use in small cats ≤4 kg and ferrets) 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 this 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 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 3.5 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 heartworm 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.

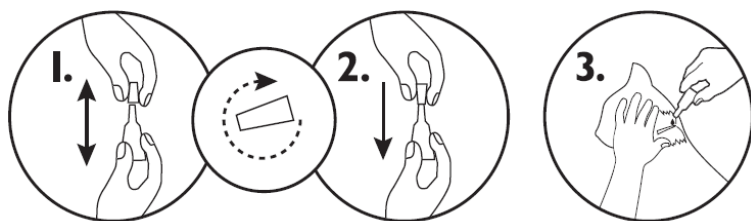
In non-endemic areas there should be no risk of cats having heartworm. Therefore they can be treated without special precautions.

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.

Method of administration:

1. Remove the pipette from its packaging. Hold the pipette in an upright position, twist and pull the cap off.
2. Turn the cap around and place the other end of the cap back on the pipette. Push and twist the cap to break the seal, then remove the cap from the pipette.
3. Part the coat on the animal's neck at the base of the skull until the skin is visible. Place the tip of the pipette onto the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot. Avoid contact between the veterinary medicinal product and your fingers.



Application at the base of the skull will minimise the opportunity for the animal to lick the veterinary medicinal product. The veterinary medicinal product should only be applied to undamaged skin.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

The combination of imidacloprid and moxidectin was administered to kittens at up to 5 times the recommended dose, every 2 weeks for 6 treatments, and there were no serious safety concerns.

Transient mydriasis, salivation, vomiting and transient rapid respiration were observed.

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

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QP54AB52.

4.2 Pharmacodynamics

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 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 veterinary medicinal product. Imidacloprid has a high affinity for the nicotinic 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 nicotinic 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 cats for 4 weeks after a single application against reinfection with *Dirofilaria immitis*.

4.3 Pharmacokinetics

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 1 to 2 days after treatment in cats. Following absorption from the skin, moxidectin is distributed systemically and is slowly eliminated from the plasma as manifested by detectable moxidectin concentrations in plasma throughout the treatment interval of one month.

The mean $T_{1/2}$ in cats ranges between 18.7 and 25.7 days.

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

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.

5.4 Nature and composition of immediate packaging

A white polypropylene (PP) unit dose pipette with a closure with a spike composed of high density polyethylene (HDPE) or polyoxymethylene (POM) or polypropylene (PP) packed into a laminated triplex bag composed of polyester (PETP), aluminium (Al) and low density polyethylene (LDPE).

Cardboard box containing 1, 3, 4, 6, 24 or 48 pipettes.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

The 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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**BOX****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Prinocate 80 mg/8 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.8 ml pipette contains: 80 mg imidacloprid, 8 mg moxidectin.

3. PACKAGE SIZE

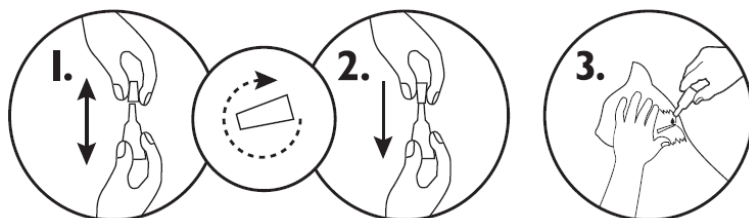
1 x 0.8 ml
3 x 0.8 ml
4 x 0.8 ml
6 x 0.8 ml
24 x 0.8 ml
48 x 0.8 ml

4. TARGET SPECIES

Cats (>4-8 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 NUMBERS
--

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**BAG****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Prinocate

>4-8 kg

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

imidacloprid/moxidectin

80 mg/8 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

>4-8 kg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Prinocate 40 mg/4 mg spot-on solution for small cats and ferrets

Prinocate 80 mg/8 mg spot-on solution for large cats

2. Composition

Active substances, excipients:

	Volume [ml]	Imidacloprid [mg]	Moxidectin [mg]	Butylhydroxytoluene (E 321) [mg]	Benzyl alcohol (E 1519) [mg]
Prinocate for small cats and ferrets	0.4	40	4	0.4	329
Prinocate for large cats	0.8	80	8	0.8	658

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

3. Target species

Small cats (≤ 4 kg) and ferrets.

Large cats (>4 -8 kg).



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 cases of hypersensitivity to the active substances or to any of the excipients.

For ferrets and small cats: Do not use the veterinary medicinal product for large cats (0.8 ml) or for dogs (any size).

For dogs, the corresponding veterinary medicinal 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:

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 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").

Special precautions for safe use in the target species:

The 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.

The veterinary medicinal product should only be applied to undamaged skin.

Care should be taken that the content 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.

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, before beginning

prophylactic treatment, as use of the veterinary medicinal product on cats or ferrets which have adult heartworms 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:

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.

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.

Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

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

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

Overdose:

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

The combination of imidacloprid and moxidectin was administered to kittens at up to 5 times the recommended dose, every 2 weeks for 6 treatments, and there were no serious safety concerns.

Transient mydriasis, salivation, vomiting and transient rapid respiration were observed.

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

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

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

Cats, ferrets:

Rare (1 to 10 animals / 10,000 animals treated):
Vomiting ¹ Application site greasy fur ¹ , Application site erythema (redness) ¹ , Hypersensitivity reaction ² .
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Behavioural disorders (e.g. agitation, inappetence, lethargy) ³ Neurological signs ⁴
Undetermined frequency (cannot be estimated from the available data):
Pruritus (itching) ⁵ Hypersalivation ⁶

¹These signs disappear without further treatment.

²Local.

³Transiently noted and related to sensation at application site.

⁴Most occur transiently and if animal licks the application site after treatment (see section “Overdose”).

⁵In cats, transient.

⁶Occurs 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 veterinary medicinal 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 its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

For external use only (spot-on use).

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:

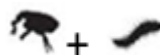
The recommended minimum doses are 10 mg/kg bodyweight imidacloprid and 1.0 mg/kg bodyweight moxidectin, equivalent to 0.1 ml/kg bodyweight.

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

Administer in accordance with the following table:

Cats [kg]	Pipette size to be used	Volume [ml]	Imidacloprid [mg/kg b.w.]	Moxidectin [mg/kg b.w.]
≤4	imidacloprid/moxidectin 40 mg/4 mg spot-on solution for small cats and ferrets	0.4	minimum of 10	minimum of 1
>4-8	imidacloprid/moxidectin 80 mg/8 mg spot-on solution for large cats	0.8	10-20	1-2
>8	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 this 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 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 warnings” 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 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 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 the veterinary medicinal product for use in small cats and ferrets (0.4 ml) should be administered per animal.

Do not exceed the recommended dose.

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

Flea treatment and prevention (*Ctenocephalides felis*):

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

Heartworm prevention (*Dirofilaria immitis*):

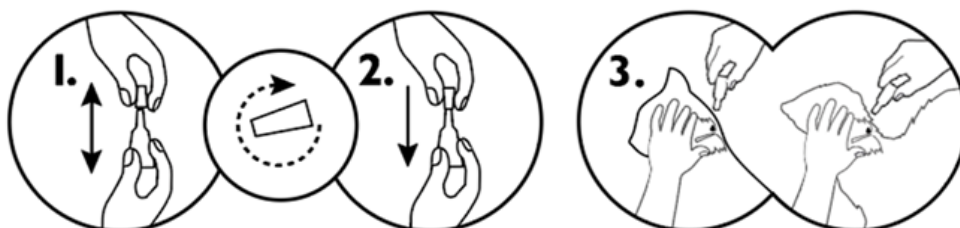
Ferrets in areas endemic for heartworm, or those which have travelled to endemic areas, may be infected with adult heartworms. Therefore prior to treatment with the veterinary medicinal product, the advice provided in section “Special warnings” should be considered.

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 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. 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

How to apply:

1. Remove the pipette from its packaging. Hold the pipette in an upright position, twist and pull the cap off.
2. Turn the cap around and place the other end of the cap back on the pipette. Push and twist the cap to break the seal, then remove the cap from the pipette.
3. Part the coat on the animal's neck at the base of the skull until the skin is visible. Place the tip of the pipette onto the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot. Avoid contact between the veterinary medicinal product and your fingers.



Application at the base of the skull will minimise the opportunity for the animal to lick the veterinary medicinal product. The veterinary medicinal product should only be applied to undamaged skin.

10. **Withdrawal periods**

Not applicable.

11. **Special storage precautions**

Keep out of the sight and reach of children.

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

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

Pack sizes:

Cardboard box containing 1, 3, 4, 6, 24 or 48 pipettes.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Local representatives and contact details to report suspected adverse events:

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

17. Other information