ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.4 ml pipette contains:

Active substances:

Imidacloprid	40 mg
Moxidectin	4 mg

3. PHARMACEUTICAL FORM

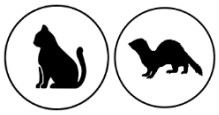
Spot-on solution

4. PACKAGE SIZE

1x 0.4 ml
3 x 0.4 ml
4 x 0.4 ml
6 x 0.4 ml
24 x 0.4 ml
48 x 0.4 ml

5. TARGET SPECIES

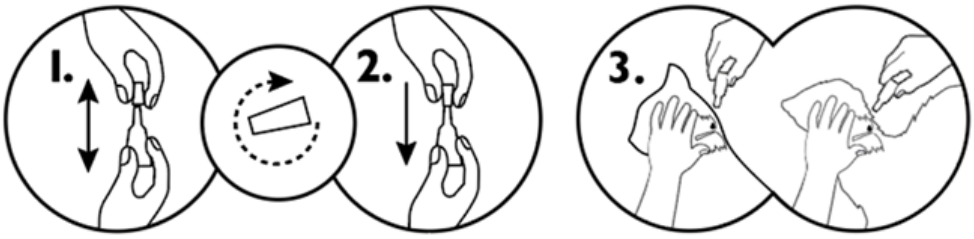
Cats (≤ 4 kg) and ferrets.



6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on use.
Read the package leaflet before use.



8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

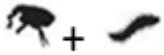
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01656/4181

17. MANUFACTURER'S BATCH NUMBER

Lot {number}


Ctenocephalides felis

Otodectes cynotis

Notoedres cati

Eucoleus aerophilus (syn. Capillaria aerophila)

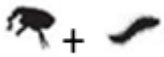
Aelurostrongylus abstrusus

Thelazia callipaeda

Dirofilaria immitis

Toxocara cati

Ancylostoma tubaeforme


Ctenocephalides felis

Dirofilaria immitis

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BAG

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

40 mg/4 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

0.4 ml

4. ROUTE(S) OF ADMINISTRATION

Spot on use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PIPETTE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prinocate 40 mg/4 mg
Imidacloprid/Moxidectin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

0.4 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD(S)

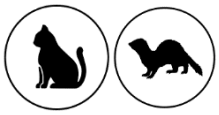
6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”



B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Prinocate 40 mg/4 mg spot-on solution for small cats and ferrets
Prinocate 80 mg/8 mg spot-on solution for large cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

2. 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
Imidacloprid/Moxidectin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each pipette contains:

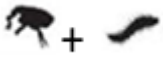
Active substances, excipients:

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

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

4. INDICATION(S)

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 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: 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. ADVERSE REACTIONS

Use of the product may result in transient pruritus in cats. On rare occasions greasy fur, erythema and vomiting can occur. These signs disappear without further treatment. The product may, in rare cases, cause local hypersensitivity reactions. If the animal licks the application site after treatment, 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 be observed in very rare cases.

The 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.

The product may in very rare cases cause at the application site a sensation resulting in transient behavioural changes such as lethargy, agitation, and inappetence.

In case of accidental oral uptake, symptomatic treatment should be performed by a veterinary surgeon. There is no known specific antidote. The use of activated charcoal may be beneficial.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)

- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cats. Ferrets (40 mg/4 mg product only).

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

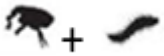
Dosage schedule for cats:

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 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 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 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 product should be administered.

Treatment of the lungworm *Eucoleus aerophilus* (syn. *Capillaria aerophila*) (adults):

A single dose of the product should be administered.

Prevention of *Aelurostrongylus abstrusus*:

The product should be administered monthly.

Treatment of *Aelurostrongylus abstrusus*:

The product should be administered monthly for three consecutive months.

Treatment of the eye worm *Thelazia callipaeda* (adults):

A single dose of the 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 product, the advice provided in section SPECIAL WARNING(S) should be considered.
For prevention of heartworm disease, the 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 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 product in a heartworm prevention programme, the first treatment with this 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 product can be used as part of a seasonal prevention programme against fleas and gastrointestinal nematodes.

Dosage schedule for ferrets:

One pipette of the 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*):

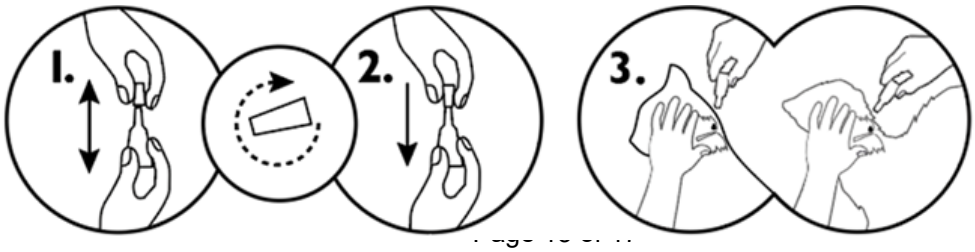
Ferrets in areas endemic for heartworm, or those which have travelled to endemic areas, may be infected with adult heartworms. Therefore prior to treatment with the product, the advice provided in section 12 should be considered.

For prevention of heartworm disease, the 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 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 product and your fingers.



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

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in the original package in order to protect from light and moisture. 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 WARNING(S)

Special warnings for each target species:
The product's efficacy has not been tested in ferrets weighing over 2 kg and therefore the duration of effect might be shorter in these animals.

Brief contact of the animal with water on one or two occasions between monthly treatments is unlikely to significantly reduce the efficacy of the product. However, frequent shampooing or immersion of the animal in water after treatment may reduce the efficacy of the product.
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 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 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 INDICATION(S) and DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION).

Special precautions for use in animals:
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 product in sick and debilitated animals, thus the product should only be used based on a benefit-risk assessment for these animals.
The 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. Oral uptake by Collie or Old English Sheep dogs and related breeds or crossbreeds should be prevented.
It is recommended that cats and ferrets living in, or travelling to areas endemic for heartworm are treated monthly with the 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 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 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 product with caution. In very rare cases the product may cause skin sensitisation or transient skin reactions (for example numbness, irritation or burning/tingling sensation).
In very rare cases the product may cause respiratory irritation in sensitive individuals.
If the 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 product in the evening. Recently treated animals should not be allowed to sleep in the same bed as their owner, especially children.

The solvent in the 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 (symptoms, emergency procedures, 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.
The combination 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.

Incompatibilities:
Not applicable.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via household waste. The product should not enter water courses as this may be dangerous for fish and other aquatic organisms. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Imidacloprid is effective against larval flea stages and adult fleas. Flea larvae in the pet’s surroundings are killed after contact with a pet treated with the product.

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 polyetylene (LDPE).
Cardboard box containing 1, 3, 4, 6, 24 or 48 pipettes.

Not all pack sizes may be marketed.

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

Local representative:
Krka UK Ltd
United Kingdom
Tel: 0207 164 6156
pharmacovigilance.uk@krka.biz

Unlimited Renewal: May 2024
AN: 00282/2024

Approved: 15 May 2024