SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prinovox 80 mg + 8 mg spot-on solution for large cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.8 ml pipette contains:

Active substance(s):

Imidacloprid	80.0 mg
Moxidectin	8.0 mg

Excipient(s):

Butylhydroxytoluene (E 321)	0.8 mg
Benzyl alcohol	657.2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.
Clear yellow to brownish solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats (> 4–8 kg)

4.2 Indications for use, specifying the 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 lungworm *Troglostrongylus brevior* (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).

4.3 Contraindications

Do not use in kittens under 9 weeks of age.

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

For ferrets: Do not use Prinovox for large cats (0.8 ml) or Prinovox for dogs (any size).

For dogs, the corresponding “Prinovox for dog” product, which contains 100 mg/ml imidacloprid and 25 mg/ml moxidectin, 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 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 4.2 and 4.9).

4.5 Special precautions for use

i) Special precautions for use in animals

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.

Do not apply in the mouth, in the eyes or the ears of the animal.

Care should be taken that the 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 product should be applied at the base of the skull in order to minimise the risk for the animal to lick the 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.

It is recommended that cats 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 aged over 6 months, before beginning prophylactic treatment, as use of the 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 product alone may not be sufficient to prevent death of the animal.

The safety of the product has not been established in cats with severe clinical signs of *T. brevior*. Use of the product in such cases should be based on the benefit-risk assessment of the veterinarian.

Imidacloprid is toxic for birds, especially canaries.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Avoid contact with skin, eyes or mouth.
Do not eat, drink or smoke during application.
Wash hands thoroughly after use.
Ingestion of the product is harmful. 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.
After application, treated animals should not be handled, especially by children 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.
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.
In case of accidental ingestion of the product or if skin or eye symptoms persist, seek medical advice immediately and show the package leaflet or the label to the physician.

iii) Other precautions

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.

4.6 Adverse reactions (frequency and seriousness)

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) may be observed in very rare cases (see section 4.10).

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.

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).

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 this veterinary medicinal product no other antiparasitic macrocyclic lactone should be administered.

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

4.9 Amounts to be administered and administration route

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 of this product per kg bodyweight.

The body weight of treated cats should be determined prior to treatment.

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

Weight of cat [kg]	Pipette size to be used	Volume [ml]	Imidacloprid [mg/kg bw]	Moxidectin [mg/kg bw]
> 4–8 kg	Prinovox for large cats	0.8	10–20	1–2
> 8 kg	the appropriate combination of pipettes			
Cats weighing less than 4 kg bodyweight: use Prinovox spot-on solution for small cats and ferrets				

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 the treatment with this 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 Troglostrongylus brevior (adults)

The product should be administered monthly for two 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 this product, the advice provided in section 4.5 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. 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 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.

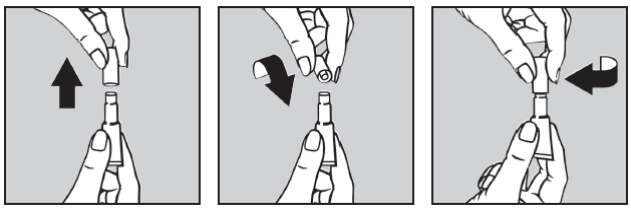
Roundworm and hookworm treatment

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.

Method of administration

For external use only.

Remove one pipette from the package. Then hold the pipette in an upright position, and twist and pull off the cap. Reverse the cap and use it to twist and remove the seal from the pipette, as shown.



Part the fur on the animal's neck at the base of the skull until the skin is visible. Place the tip of the pipette on the skin and squeeze the pipette firmly several times to empty its contents directly onto the skin. Application at the base of the skull will minimise the opportunity for the animal to lick the product. Apply only to undamaged skin.

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

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

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 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. 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 product has a persistent action and protects cats for 4 weeks after a single application against reinfection with *Dirofilaria immitis*.

5.2 Pharmacokinetic particulars

After topical administration of the 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 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 mean T ½ 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.

5.3 Environmental properties

Moxidectin fulfils the criteria for a persistent, bioaccumulative and toxic substance; therefore, exposure of the environment to moxidectin should be minimised as much as possible. The product should not enter water courses as it has harmful effects on aquatic organisms. Moxidectin is highly toxic to aquatic organisms.
See also section 6.6.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene (E 321)
Benzyl alcohol
Propylene carbonate

6.2 Major incompatibilities

None known.

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and composition of immediate packaging

White polypropylene pipettes closed with a screw cap.
Blister packs containing 1, 2, 3, 4, 6 or 21 pipettes.
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

The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

[*to be completed*]

8. MARKETING AUTHORISATION NUMBER(S)

[*to be completed*]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: [*to be completed*]

10. DATE OF REVISION OF THE TEXT

[*to be completed*]

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Outer carton, pack size of 1, 2, 3, 4, 6 or 21 pipettes.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prinovox 80 mg + 8 mg spot-on solution for large cats
Imidacloprid, Moxidectin

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.8 ml pipette contains 80.0 mg imidacloprid and 8.0 mg moxidectin as active substances

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1 pipette
2 pipettes
3 pipettes
4 pipettes
6 pipettes
21 pipettes

5. TARGET SPECIES

For large cats weighing between 4 kg and 8 kg.

6. INDICATION(S)

 Fleas  Worms  Mites

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 lungworm *Troglostrongylus brevior* (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).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Do not use in kittens under 9 weeks of age. Consult your veterinarian before using the product on pregnant or lactating cats, or on sick or debilitated cats.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

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

The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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

Marketing authorisation holder:
[*to be completed*]

Distributed by:
[*to be completed*]

Manufacturer responsible for batch release:
KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324, 24106 Kiel
Germany

16. MARKETING AUTHORISATION NUMBER(S)

[*to be completed*]

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Pipette label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prinovox spot-on for large cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Imidacloprid(e) 80.0 mg, Moxidectin 8.0 mg

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

0.8 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prinovox spot-on for large cats
(> 4–8 kg)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[*to be completed if nationally required*]
Distributed by [*to be completed*]

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Prinovox 40 mg + 4 mg spot-on solution for small cats and ferrets
Prinovox 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:
[*to be completed*]

Distributed by:
[*to be completed*]

Manufacturer responsible for batch release:
KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324, 24106 Kiel
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prinovox 40 mg + 4 mg spot-on solution for small cats and ferrets
Prinovox 80 mg + 8 mg spot-on solution for large cats
Imidacloprid, Moxidectin

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

Each 0.4 ml / 0.8 ml pipette contains:

Active substance(s):

Imidacloprid	40.0 mg / 80.0 mg
Moxidectin	4.0 mg / 8.0 mg

Excipient(s):

Butylhydroxytoluene (E 321)	0.4 mg / 0.8 mg
Benzyl alcohol	328.6 mg / 657.2 mg

A clear yellow to brownish spot-on 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 lungworm *Troglostrongylus brevior* (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 known hypersensitivity to the active substances or to any of the excipients.

For ferrets: Do not use Prinovox for large cats (0.8 ml) or Prinovox for dogs (any size).

For dogs, the corresponding "Prinovox for dogs" 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.
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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.

7. TARGET SPECIES

Cats, ferrets

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For external use only.

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 of the product per kg bodyweight.

The body weight of treated cats should be determined prior to treatment.

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

Weight of cat [kg]	Pipette size to be used	Volume [ml]	Imidacloprid [mg/kg bw]	Moxidectin [mg/kg bw]
≤ 4 kg	Prinovox for small cats and ferrets	0.4	minimum of 10	minimum of 1
> 4–8 kg	Prinovox for large cats	0.8	10–20	1–2
> 8 kg	appropriate combination of pipettes			

Flea treatment and prevention (Ctenocephalides felis)

One treatment prevents further flea infestation for 4 weeks. Pre-existing pupae in the environment may continue to emerge for 6 weeks or longer after treatment is initiated depending upon climatic conditions. Therefore, it may be necessary to combine the treatment with this product with environmental treatments aimed at breaking the flea life cycle in the surroundings. This can result in more rapid reductions 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 Troglostrongylus brevior (adults)

The product should be administered monthly for two 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 endemic areas, or those which have travelled to endemic areas, may be infected with adult heartworms. Therefore prior to treatment with this product, the advice provided in the 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. The first dose may be given after first possible exposure to mosquitoes, but not more than one month after this exposure. The 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 considerations.

Roundworm and hookworm treatment

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 0.4 ml pipette of this product 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.

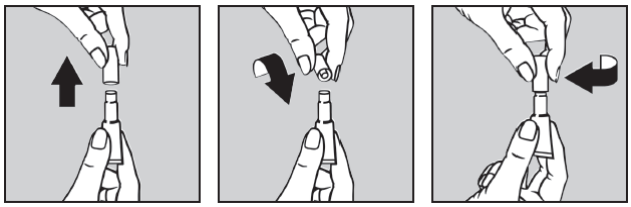
Heartworm prevention (Dirofilaria immitis)

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 this product, the advice provided in the section "SPECIAL WARNING(S)" should be considered.

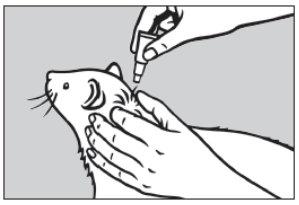
For prevention of heartworm disease, the product must be applied at regular monthly intervals during the time of the year when mosquitoes (the intermediate hosts which carry and transmit heartworm larvae) are present. The product may be administered throughout the year. The first dose may be given after 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.
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

Remove one pipette from the package. Then hold the pipette in an upright position, and twist and pull off cap. Reverse the cap and use it to twist and remove the seal from the pipette, as shown.



Part the fur on the animal's neck at the base of the skull until the skin is visible. Place the tip of the pipette on the skin and squeeze the pipette firmly several times to empty its contents directly onto the skin. Application at the base of the skull will minimise the opportunity for the animal to lick the product. Apply only to undamaged skin.



10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25 °C.
Do not use this veterinary medicinal product after the expiry date stated on the label and carton. The expiry date refers to the last day of that month.

12. SPECIAL 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 “Indications” and “Dosage for each species, route and method of administration”).

Special precautions for use in animals:

Treatment of cats weighing less than 1 kg and ferrets weighing less than 0.8 kg with 'Prinovox for small cats and ferrets' 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.

Do not apply in the mouth, in the eyes or the ears of the animal.

Care should be taken that the 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 “Advice on correct administration”, especially that the product should be applied at the base of the skull in order to minimise the risk for the animal to lick the 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.

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, prior to beginning of prophylactic treatment, as use of the product on cats or ferrets which have adult heartworm 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.

The safety of the product has not been established in cats with severe clinical signs of *T. brevior*. Use of the product in such cases should be based on the benefit-risk assessment of the veterinarian.

Imidacloprid is toxic for birds, especially canaries.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Avoid contact with skin, eyes or mouth.
Do not eat, drink or smoke during application.
Ingestion of the product is harmful. 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.
Wash hands thoroughly after use.

After application, treated animals should not be handled, especially by children 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.
People with a 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 case the product may cause respiratory irritation in sensitive individuals.
If the product accidentally gets into eyes, they should be thoroughly flushed with water.
In case of accidental ingestion of the product or if skin or eye symptoms persist, seek medical advice immediately and show the package leaflet or the label to the physician.

Environmental information/warnings

Moxidectin fulfils the criteria for a persistent, bioaccumulative and toxic substance; therefore, exposure of the environment to moxidectin should be minimised as much as possible. The product should not enter water courses as it has harmful effects on aquatic organisms. Moxidectin is highly toxic to aquatic organisms.

Other precautions

The solvent in this product may stain or damage certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in the target species. Therefore, the use of the product is not recommended in animals intended for breeding or during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

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

No interactions between this 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 product 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 product 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:

None known.

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

Medicines should not be disposed of via wastewateror 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.

The product has a persistent action and protects cats for 4 weeks after a single application against reinfection with *Dirofilaria immitis*.
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.

Pack sizes: 0.4 ml and 0.8 ml per pipette.
Blister packs containing 1, 2, 3, 4, 6 or 21 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.