[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prinovox 40 mg + 4 mg spot-on solution for small cats and ferrets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.4 ml pipette contains:

Active substances:
Imidacloprid 40.0 mg
Moxidectin 4.0 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 (E1519)	328.6 mg
Butylhydroxytoluene (E321)	0.4 mg
Propylene carbonate	

Clear yellow to brownish solution.

3. CLINICAL INFORMATION

3.1 Target species

Cats (≤ 4 kg), ferrets.

3.2 Indications for use for each target species

For cats suffering from, or at risk from, mixed parasitic infections. The veterinary medicinal product is only indicated when use against fleas and one or more of the other target parasites is indicated at the same time.

- 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 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 veterinary medicinal product is only indicated when use against fleas and the prevention of heartworm disease is indicated at the same time.

- the treatment and prevention of flea infestation (*Ctenocephalides felis*),

- the prevention of heartworm disease (L3 and L4 larvae of *Dirofilaria immitis*).

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.

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

Do not use in dogs. Instead, the corresponding "Prinovox for dogs" product, which contains 100 mg/ml imidacloprid and 25 mg/ml moxidectin, must be used for dogs.

Do not use on canaries.

3.4 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.

The possibility that other animals in the same household can be a source of re-infection with fleas, mites, gastrointestinal nematodes, heartworm and/or lungworm should be considered, and these should be treated as necessary with an appropriate product.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.

3.5 Special precautions for use

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.

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

Care should be taken that the veterinary medicinal product is not ingested by animals and does not come into contact with the eyes or mouth of the recipient and/or other animals.

Consider carefully the correct application method described in section 3.9, especially that the veterinary medicinal product should be applied at the base of the skull in order to minimise the risk for the animal to lick the veterinary medicinal product.

Do not allow recently treated animals to groom each other. Do not allow treated animals to come into contact with untreated animals until the application site is dry.

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.

The safety of the veterinary medicinal product has not been established in cats with severe clinical signs of *T. brevior*. Use of the veterinary medicinal 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:
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.
People with known hypersensitivity to benzyl alcohol, imidacloprid or moxidectin should administer the veterinary medicinal product with caution.
Ingestion of the veterinary medicinal 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 children, until the application site is dry. This can be ensured by treating animals in the evening. Do not allow recently treated animals to sleep with owners, especially children.
Avoid contact with skin, eyes or mouth.
In case of accidental spillage onto skin, wash off immediately with soap and water.
If the veterinary medicinal product accidentally gets into eyes, they should be thoroughly flushed with water.
If skin or eye symptoms persist, or the veterinary medicinal product is accidentally swallowed, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not eat, drink or smoke during application.
Wash hands thoroughly after use.

Special precautions for the protection of the environment:
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 veterinary medicinal product should not enter water courses as it has harmful effects on aquatic organisms.
Moxidectin is highly toxic to aquatic organisms.
See also section 5.5.

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 and ferrets:

Rare (1 to 10 animals / 10,000 animals treated):	Application site greasy fur[1] Vomiting[1] Hypersensitivity reaction (local) Erythema[1]
Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Behavioural disorder (e.g. Agitation, Lethargy, Inappetence)[2] Hypersalivation[3] Neurological signs[4] Pruritus[5]

[1] Disappear without further treatment.
[2] Transiently noted and related to sensation at application site.
[3] 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.
[4] If the animal licks the application site, in most cases transient.
[5] In cats, transient.

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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in the target species.

Pregnancy and lactation:
The use is not recommended during pregnancy and lactation.

Fertility:
Do not use in breeding animals.

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

Spot-on use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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 of the veterinary medicinal product.

For treatment or prevention of infestations with the parasites indicated for use of this veterinary medicinal product, the need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

Weight of 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
Cats weighing over 4 kg bodyweight: use Prinovox spot-on solution for large cats				

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 veterinary medicinal product treatment with environmental treatments aimed at breaking the flea life cycle in the surroundings. This can result in a more rapid reduction in the household flea population. The veterinary medicinal product should be administered at monthly intervals when used as part of a treatment strategy for flea allergy dermatitis.

Treatment of 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 Troglostrongylus brevior (adults)

The veterinary medicinal product should be administered monthly for two 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. The first dose may be given after first possible exposure to mosquitoes, but not more than one month after this exposure. Treatment should continue at regular monthly intervals until 1 month after the last exposure to mosquitoes. To establish a treatment routine, it is recommended that the same day or date be used each month. When replacing another heartworm preventative product in a heartworm prevention programme, the first treatment with the veterinary medicinal product must be given within 1 month of the last dose of the former veterinary medicinal product.

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 (0.4 ml) should be administered per animal. Do not exceed the recommended dose.

For treatment or prevention of infestations with the parasites indicated for use of this veterinary medicinal product, the need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

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)

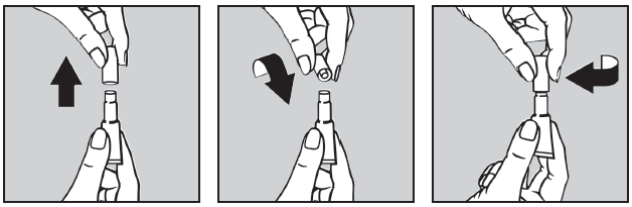
Ferrets in areas endemic for heartworm, or those which have travelled to endemic areas, may be infected with adult heartworms. Therefore prior to treatment with the veterinary medicinal product, the advice provided in section 3.5 should be considered.

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. 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.

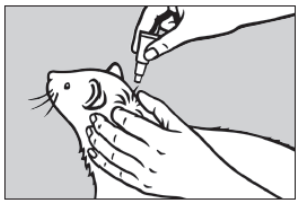
Method of administration

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 veterinary medicinal product. Apply only 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 veterinary medicinal 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 veterinary medicinal 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.

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 nicotinergic acetylcholine receptors in the post-synaptic region of the central nervous system (CNS) of the flea. The ensuing inhibition of cholinergic transmission in insects results in paralysis and death. Due to the weak nature of the interaction with mammalian nicotinergic receptors and the postulated poor penetration through the blood-brain barrier in mammals, it has virtually no effect on the mammalian CNS. Imidacloprid has minimal pharmacological activity in mammals.

Moxidectin, 23-(O-methyloxime)-F28249 alpha is a second-generation macrocyclic lactone of the milbemycin family. It is a parasiticide which is active against many internal and external parasites. Moxidectin is active against larval stages (L3, L4) of *Dirofilaria immitis.* It is also active against gastrointestinal nematodes. Moxidectin interacts with GABA and glutamate-gated chloride channels. This leads to opening of the chloride channels on the postsynaptic junction, the inflow of chloride ions and induction of an irreversible resting state. The result is flaccid paralysis of affected parasites, followed by their death and/or expulsion. The veterinary medicinal product has a persistent action and protects 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 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. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

White polypropylene pipette for single use closed with a white polypropylene screw cap. Pipettes are packed in polyvinyl chloride and aluminium foil blisters. Each pipette contains 0.4 ml of solution.

Pack sizes:
Cardboard box containing blister packs with 1, 2, 3, 4, 6 or 21 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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD month YYYY}

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

{DD month 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*).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (pack size of 1, 2, 3, 4, 6 or 21 pipettes)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prinovox 40 mg + 4 mg spot-on solution for small cats and ferrets

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.4 ml pipette contains:

Active substances:
Imidacloprid 40.0 mg
Moxidectin 4.0 mg

3. PACKAGE SIZE

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

4. TARGET SPECIES

Cats (≤ 4 kg) and ferrets.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Spot-on use.
For external use only.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

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

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PIPETTE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prinovox (≤ 4 kg)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

0.4 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prinovox (≤ 4 kg)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Imidacloprid 40.0 mg, Moxidectin 4.0 mg

0.4 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. 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

2. Composition

Each pipette contains:

		Active substances:		Excipients:	
	Unit Dose	**Imidacloprid**	**Moxidectin**	**Butylhydroxytoluene (E 321)**	**Benzyl alcohol (E 1519)**
Prinovox for small cats (≤ 4 kg) and ferrets	0.4 ml	40.0 mg	4.0 mg	0.4 mg	328.6 mg
Prinovox for large cats (> 4–8 kg)	0.8 ml	80.0 mg	8.0 mg	0.8 mg	657.2 mg

Clear yellow to brownish solution.

3. Target species

Cats and ferrets.

4. Indications for use

For cats suffering from, or at risk from, mixed parasitic infections. The veterinary medicinal product is only indicated when use against fleas and one or more of the other target parasites is indicated at the same time.

- 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 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 veterinary medicinal product is only indicated when use against fleas and the prevention of heartworm disease is indicated at the same time.

- 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 Prinovox for large cats (0.8 ml) or Prinovox for dogs (any size).

Do not use in dogs. Instead, the corresponding "Prinovox for dogs" product, which contains 100 mg/ml imidacloprid and 25 mg/ml moxidectin, must be used for dogs.

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.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.

The possibility that other animals in the same household can be a source of re-infection with fleas, mites, gastrointestinal nematodes, heartworm and/or lungworm should be considered, and these should be treated as necessary with an appropriate product.

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.

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

Care should be taken that the veterinary medicinal product is not ingested by animals and does not come into contact with the eyes or mouth of the recipient and/or other animals.

Consider carefully the correct application method described in the "Advice on correct administration" section, especially that the veterinary medicinal product should be applied at the base of the skull in order to minimise the risk for the animal to lick the veterinary medicinal product.

Do not allow recently treated animals to groom each other. Do not allow treated animals to come into contact with untreated animals until the application site is dry.

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.

The safety of the veterinary medicinal product has not been established in cats with severe clinical signs of *T. brevior*. Use of the veterinary medicinal 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:

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.
People with known hypersensitivity to benzyl alcohol, imidacloprid or moxidectin should administer the veterinary medicinal product with caution.
Ingestion of the veterinary medicinal 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 children, until the application site is dry. This can be ensured by treating animals in the evening. Do not allow recently treated animals to sleep with owners, especially children.
Avoid contact with skin, eyes or mouth.
In case of accidental spillage onto skin, wash off immediately with soap and water.
If the veterinary medicinal product accidentally gets into eyes, they should be thoroughly flushed with water.
If skin or eye symptoms persist, or the veterinary medicinal product is accidentally swallowed, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not eat, drink or smoke during application.
Wash hands thoroughly after use.

Special precautions for the protection of the environment:

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 veterinary medicinal product should not enter water courses as it has harmful effects on aquatic organisms. Moxidectin is highly toxic to aquatic organisms.

See also “Special precautions for disposal”.

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 in the target species.

The use is not recommended during pregnancy and lactation.

Fertility:

Do not use in breeding animals.

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 veterinary medicinal 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 veterinary medicinal 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.

7. Adverse events

Cats and ferrets:

Rare (1 to 10 animals / 10,000 animals treated):
Application site greasy fur[1] Vomiting[1] Hypersensitivity reaction (local) Erythema[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):

Behavioural disorder (e.g. Agitation, Inappetence, Lethargy)[2] Hypersalivation[3] Neurological signs[4] Pruritus[5] (itching)

[1] Disappear without further treatment.
[2] Transiently noted and related to sensation at application site.
[3] 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.
[4] If the animal licks the application site, in most cases transient.
[5] In cats, transient

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or 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

Spot-on use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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 of the veterinary medicinal product.

For treatment or prevention of infestations with the parasites indicated for use of this veterinary medicinal product, the need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

Weight of 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 future flea infestation for 4 weeks. Existing pupae in the environment may emergefor 6 weeks or longer after treatment is initiated, depending upon climatic conditions. Therefore, it may be necessary to combine veterinary medicinal product treatment with environmental treatments aimed at breaking the flea life cycle in the surroundings. This can result in a more rapid reduction in the household flea population. The veterinary medicinal product should be administered at monthly intervals when used as part of a treatment strategy for flea allergy dermatitis.

Treatment of 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 Troglostrongylus brevior (adults)

The veterinary medicinal product should be administered monthly for two 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 the "Special Warnings" section 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. The first dose may be given after first possible exposure to mosquitoes, but not more than one month after this exposure. Treatment should continue at regular monthly intervals until 1 month after the last exposure to mosquitoes. To establish a treatment routine, it is recommended that the same day or date be used each month. When replacing another heartworm preventative product in a heartworm prevention programme, the first treatment with the veterinary medicinal product must be given within 1 month of the last dose of the former medication.

In non-endemic areas there should be no risk of 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 Small Cats (0.4 ml) should be administered per animal. Do not exceed the recommended dose.

For treatment or prevention of infestations with the parasites indicated for use of this veterinary medicinal product, the need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

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)

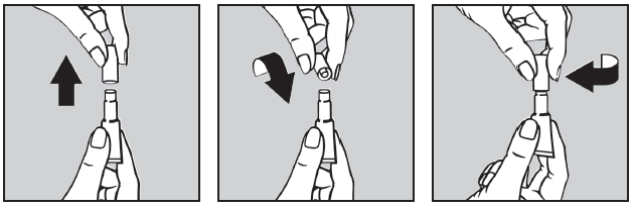
Ferrets in areas endemic for heartworm, or those which have travelled to endemic areas, may be infected with adult heartworms. Therefore prior to treatment with the veterinary medicinal product, the advice provided in the "Special Warnings" section should be considered.

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. 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.

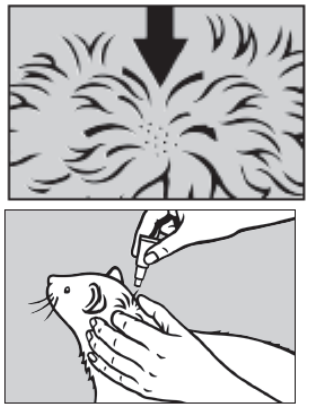
9. Advice on correct administration

For external use only.

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 periods

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 which is stated on the label and carton 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.

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 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

Prinovox 40 mg + 4 mg spot-on solution for small cats and ferrets
No.

Prinovox 80 mg + 8 mg spot-on solution for large cats
No.
Pack sizes:
Cardboard box containing blister packs with 1, 2, 3, 4, 6 or 21 pipettes.
Each pipette contains 0.4 ml or 0.8 ml of solution.

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*).

16. Contact details

Marketing authorisation holder:

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

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

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.

The veterinary medicinal 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.