Prinovox®

Prinovox Spot-on solution for cats and ferrets — PACKAGE LEAFLET

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

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.

Indication(s)
***For cats* suffering from, or at risk from, mixed parasitic infections:**
- For 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 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:**
- For the treatment and prevention of flea infestation (*Ctenocephalides felis*),
- the prevention of heartworm disease (L3 and L4 larvae of *Dirofilaria immitis*).

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.

Do not use on canaries.

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.

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.

Target Species
Cats, ferrets

Dosage for each species, route 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.

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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.

Heartworm prevention
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 or at least 1 month before the first expected exposure to mosquitoes. 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.

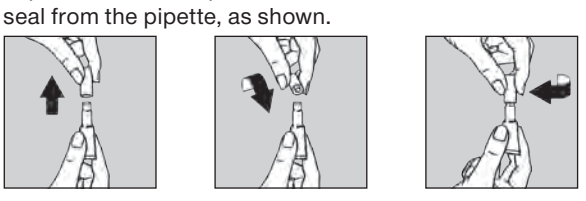
Flea treatment and prevention
One treatment prevents future flea infestation for 3 weeks. Under heavy flea pressure it may be necessary to repeat administration after 2 weeks.

Heartworm prevention
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 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.

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.

Withdrawal period
Not applicable.

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.

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 **"INDICATIONS"** and **"DOSAGE"** sections).

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.

Care should be taken that the contents of the pipette do 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 Collies, Old English Sheepdogs 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, 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.

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.

Wash hands thoroughly after use.

After application do not stroke or groom animals until the application site is dry.

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 cases the product may cause respiratory irritation in sensitive individuals.

If the product accidentally gets into eyes, they should be thoroughly flushed with water.

If skin or eye symptoms persist, or the product is accidentally swallowed, seek medical advice immediately and show the package leaflet or the label to the physician.

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. Laboratory studies with either imidacloprid or moxidectin in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

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.

Special Precautions for the disposal of unused product or waste materials, if any
Medicines should not be disposed of via wastewater. 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. Dispose of waste material in accordance with local requirements.

Date on which the package leaflet was last approved

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.

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

Not all pack sizes may be marketed.

For animal treatment only.

To be supplied only on veterinary prescription.

	UK POM-V To be supplied only on veterinary prescription	IE POM Prescription only medicine
Prinovox 40 mg + 4 mg Spot-on solution for small cats and ferrets	Vm 00010/4188	VPA 10021/074/001
Prinovox 80 mg + 8 mg Spot-on solution for large cats	Vm 00010/4189	VPA 10021/074/002

For any information about this veterinary medicinal product, please contact the distributor.

Marketing authorisation holder:

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