Drug for Animal Use Only

MORTECT for CATS

Name of the Product

MORTECT Spot-On Solution for Small Cats(0.4ml)

MORTECT Spot-On Solution for Large Cats(0.8ml)

Name and Strength of Active Substance

0.4ml : Imidacloprid 40mg + Moxidectin 4mg

0.8 ml: Imidacloprid 80 mg + Moxidectin 8 mg

Product Description

Pale yellow to yellow solution.

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 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.

Pharmacokinetic Properties

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 t½ 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.

Indication

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 are indicated at the same time.

◊ For the treatment and prevention of flea infestation (Ctenocephalides felis).

◊ For the treatment of ear mite infestation (Otodectes cynotis).

◊ For the treatment of notoedric mange (Notoedres cati).

◊ For the treatment of the lungworm Eucoleus aerophilus (syn. Capillaria aerophila) (adults).

◊ For the prevention of lungworm disease (L3/L4 larvae of Aelurostrongylus abstrusus).

◊ For the treatment of the lungworm Aelurostrongylus abstrusus (adults).

◊ For the treatment of the lungworm Troglostrongylus brevior (adults).

◊ For the treatment of the eye worm Thelazia callipaeda (adults).

◊ For the prevention of heartworm disease (L3 and L4 larvae of Dirofilaria immitis).

◊ For 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).

Target Species

Cats

Recommended Dose

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	Pipette size to be used	Volume (ml)	Imidacloprid (mg/kg bw)	Moxidectin (mg/kg bw)
≤ 4 kg	For small cats	0.4	Minimum of 10	Minimum of 1
>4~8 kg	For large cats	0.8	10-20	1-2
>8 kg	The 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 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 warning and precautions should be considered.

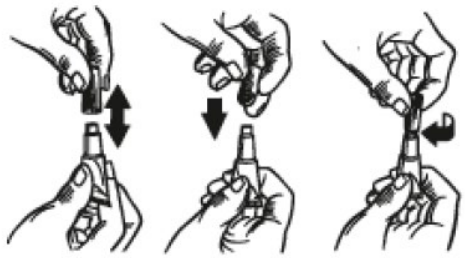
For prevention of heartworm disease, the veterinary medicinal product must be applied at regular monthly intervals during the time of the year when mosquitoes (the intermediate hosts which carry and transmit heartworm larvae) are present. The veterinary medicinal product may be administered throughout 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 nonendemic for heartworm, the veterinary medicinal product can be used as part of a seasonal prevention programme against fleas and gastrointestinal nematodes

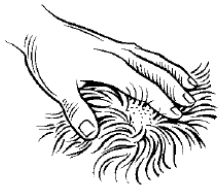
Route of Administration

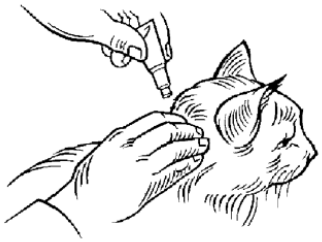
Topical/External use

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.





Contraindications

Do not use in kittens under 9 weeks of age.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use in dogs.
Do not use on canaries.

Warnings and Precautions

Special precautions for safe use in the target species:
The treatment of cats weighing less than 1 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 Recommended dose, especially that the veterinary medicinal product should be applied to the site specified 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 living in, or travelling to areas endemic for heartworm are treated monthly with the veterinary medicinal product to protect them from heartworm disease.
Whilst the accuracy of diagnosis of heartworm infection is limited, it is recommended that attempts be made to check the heartworm status of any cat aged over 6 months, before beginning prophylactic treatment, as use of the veterinary medicinal product on cats which have adult heartworms may cause serious adverse effects, including death. If adult heartworm infection is diagnosed, the infection should be treated in accordance with current scientific knowledge.
In certain individual cats Notoedres cati infestation may be severe. In these severe cases concomitant supportive treatment is necessary as treatment with the veterinary medicinal product alone may not be sufficient to prevent death of the animal.
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
This veterinary medicinal product can cause skin, eye, or mouth irritation.
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.
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. 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.

Special precautions for the protection of the environment:
The veterinary medicinal product should not enter water courses as imidacloprid and moxidectin may be dangerous for fish and other aquatic organisms.

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.

Interactions with Other Medicaments
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.

Use during pregnancy, lactation or lay
The safety of the veterinary medicinal product has not been established during pregnancy and lactation in the cats.

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

Fertility:
Do not use in breeding animals

Side Effects

Rare (1 to 10 animals / 10,000 animals treated):	Application site greasy fur1 Vomiting1 Hypersensitivity reaction (local) Erythema1
Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Behavioural disorder(e.g. agitation)2 Hypersalivation 3,4 Neurological signs3

	Pruritus5 Inappetence2, Lethargy2

1. These signs disappear without further treatment.
2 Transiently noted and related to sensation at application site.
3 If the animal licks the application site, in most cases transient.
4 This is not a sign of intoxication and disappears within minutes without treatment. Correct application will minimise licking of the application site.
5 In cats, transient.

Symptoms and Treatment of 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.

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

Storage Condition

Preserved in a tightly sealed container.
Store below 30^0C

Dosage forms and packaging available

Spot-on solutions
White polypropylene unit dose pipette closed with white polypropylene screw cap. Unit dose pipette are packed in PA/Al/PVC Cold-formed Foil and paper/Al adhesive layer blisters.
How Supplied: 0.4 ml/pipette, 0.8 ml/pipette; 3 pipettes/box.

Manufacturer：

Shanghai Hanvet Bio-Pharm Co.,Ltd.

Building 4, No. 14, 855 Lane, Jinzheng Road, Jinshan Industrial Zone, Jinshan District, Shanghai 201500, China

Product Registration Holder：

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Date of Revision of Package Insert

June, 2026