



Attachment D3 Proposed Package Insert

1.Product name

- (1) Mopsion Spot-on Solutions 0.4 mL/tube (for Cats)
- (2) Mopsion Spot-on Solutions 0.8 mL/tube (for Cats)

2. Name and Strength of Active Substance(s)

- (1) 0.4 mL/tube: Imidacloprid 40 mg+ Moxidectin 4 mg
- (2) 0.8 mL/tube: Imidacloprid 80 mg+ Moxidectin 8 mg

3. Product Description

- (1) Mopsion Spot-on Solutions 0.4 mL/tube (for Cats) is a yellow to brownish yellow solution. Each 0.4 mL tube contains 40 mg imidacloprid and 4 mg moxidectin.
- (2) Mopsion Spot-on Solutions 0.8 mL/tube (for Cats) is a yellow to brownish yellow solution. Each 0.8 mL tube contains 80 mg imidacloprid and 8 mg moxidectin.

4. (1) 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 nicotinic 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 nicotinic 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*.

(2) 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 $t_{1/2}$ 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.

(3) Environmental Properties

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as moxidectin and imidacloprid may be dangerous for fish and other aquatic organisms.

5.Target Species: Cats

6. 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 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).

7. Recommended dose

To ensure a correct dosage, body weight should be determined as accurately as possible. 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)	Applicable type	Volume (mL)	Imidacloprid (mg/kg body weight)	Moxidectin (mg/kg body weight)
≤4 kg	Small cat	0.4	Not less than 10	Not less than 1
>4~8 kg	Large cat	0.8	10~20	1~2
>8 kg	Use a combination of products of appropriate volumes			

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.

8. Mode of administration

For external use. To prevent licking, use only on the skin on the back of the cat's head and neck.

Remove one tube from the package. Then hold the tube 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 tube.

Part the fur on the animal's neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube 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.

9. Contraindication

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. Instead, the corresponding “Mopsion Spot-on Solutions (for Dogs)” product, which contains 100 mg/ml imidacloprid and 25 mg/ml moxidectin, must be used for dogs.

Do not use on canaries.

10. Warnings and Precautions

During the monthly treatment interval, brief contact with water on one or two occasions is unlikely to significantly reduce the efficacy of the veterinary medicinal product. However, frequent shampooing or prolonged immersion in water following treatment may potentially decrease its efficacy.

Consideration should be given to the possibility that other animals in the same household may act as a source of re-infestation with fleas, mites, gastrointestinal nematodes, heartworm and/or lungworm, and such animals should be treated with an appropriate product as necessary.

Unnecessary use of antiparasitic agents, or use not in accordance with the instructions, may increase antiparasitic resistance selection pressure and result in reduced efficacy.

The use of the product should be based on confirmation of the parasitic species and infestation burden, or on the risk of infestation determined by epidemiological characteristics for each individual animal.



Special precautions for safe use in the target species:

Treatment of cats weighing less than 1 kg should be based on a benefit-risk assessment.

Experience with the use of the veterinary medicinal product in sick or debilitated animals is limited; therefore, the product should only be used in these animals following a benefit-risk assessment.

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

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

Careful attention should be paid to the correct application method, the product should be applied to the specified site to minimise the risk of the animal licking the application site.

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

It is recommended that cats and ferrets living in or travelling to heartworm-endemic areas receive monthly treatment with this veterinary medicinal product for protection against heartworm disease.

Whilst the accuracy of heartworm infection diagnosis is limited, it is recommended that attempts be made to determine the heartworm status of cats and ferrets over 6 months of age before starting prophylactic treatment. Administration of this product to animals with adult heartworm infection may result in serious adverse reactions, including death. If adult heartworm infection is diagnosed, the infection should be treated in accordance with current scientific knowledge.

In some individual cats, *Notoedres cati* infestation may be severe. In such cases, concomitant supportive treatment is necessary, as treatment with this veterinary medicinal product alone may not be sufficient to prevent death.

The safety of the veterinary medicinal product has not been established in cats showing severe clinical signs associated with *Troglostrongylus brevior* infection. Use in such cases should be based on a benefit-risk assessment by the veterinarian.

Imidacloprid is toxic to birds, particularly canaries.



ringpu
瑞普生物

Ringpu (Tianjin) Bio-Pharmacy Co., Ltd.
ADD: No.6 Liujiing Road, Dongli District, Tianjin, China
Tel: +86-22-88958055

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

This veterinary medicinal product may cause irritation to the skin, eyes or mouth.

In very rare cases, the product may cause skin sensitisation or transient skin reactions such as numbness, irritation, burning or tingling.

In very rare cases, the product may cause respiratory irritation in susceptible individuals.

People with known hypersensitivity to benzyl alcohol, imidacloprid or moxidectin should administer the product with caution.

Avoid contact with skin, eyes or mouth.

Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

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

In case of accidental spillage onto the skin, wash immediately with soap and water.

If the product accidentally gets into the eyes, rinse thoroughly with water.

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

Special precautions for the protection of the environment:

The veterinary medicinal product should not be allowed to enter watercourses, as imidacloprid and moxidectin may be dangerous to fish and other aquatic organisms.

Other precautions:

The solvent contained in the veterinary medicinal product may stain or damage certain materials, including leather, fabrics, plastics and finished surfaces. Contact with such materials should be avoided until the application site is dry.

11. Interactions with other medicaments

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

No interactions have been observed between this veterinary medicinal product and



routinely used veterinary medicinal products, or during routine medical or surgical procedures.

12. 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 veterinary medicinal product is not recommended for use during pregnancy and lactation.

Fertility:

The product should not be used in breeding animals.

13. Adverse effects

Cats:

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) ² Hypersensitivity ^{3,4} Neurological signs ³ Pruritus ⁵ Inappetence ² , Lethargy ²

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.

14. Overdose and treatment

Cats tolerated doses up to 10 times the recommended level, with no evidence of adverse effects or undesirable clinical signs.

When the veterinary medicinal product was administered to kittens at up to 5 times the recommended dose, every 2 weeks for a total of 6 treatments, no serious safety concerns were identified. Transient mydriasis, salivation, vomiting, and transient rapid



ringpu
瑞普生物

Ringpu (Tianjin) Bio-Pharmacy Co., Ltd.
ADD: No.6 Liuqing Road, Dongli District, Tianjin, China
Tel: +86-22-88958055

respiration were observed.

Following accidental oral ingestion or overdose, very rare cases of neurological signs (most of which are transient) have been reported, including ataxia, generalised tremors, ocular signs (dilated pupils, minimal pupillary reflex, nystagmus), abnormal respiration, salivation, and vomiting.

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.

15. Withdrawal period(s)

Not applicable.

16. Storage conditions

Seal up, store below 25°C.

17. Shelf life

36 months

18. Dosage form and packaging

Spot-on solution.

Aluminum plastic tube, 0.4 mL/tube OR 0.8 mL/tube, 3 tubes/box.

19. Name and Address of Manufacturer

Ringpu (Tianjin) Bio-Pharmacy Co., Ltd.

Address: No.6 Liuqing Road, Dongli District, Tianjin, China

20. Name and Address of Marketing authorization holder

Medispec (M) Sdn. Bhd.

Address: B-1-07, Jalan SS 25/22, Taman Mayang, 47301 Petaling Jaya, Selangor, Malaysia

21. Date of Revision of Package Insert

May 22, 2026