

MOXAMID 40 mg/10 mg spot-on solution for small dogs S

1. Name of the veterinary medicinal product

MOXAMID 40 mg/10 mg spot-on solution for small dogs S

2. Composition

One pipette (0.4 ml) contains:

Active substances:

Imidacloprid	40 mg
Moxidectin	10 mg

Excipients:

Butylhydroxytoluene (E 321)	0.4 mg
Benzyl alcohol (E 1519)	323 mg

A clear, colourless to yellowish solution.

3. Target species

Dogs (≤ 4 kg).

4. Indications for use

For dogs suffering from, or at risk from, mixed parasitic

infections:

- the treatment and prevention of flea infestation (*Ctenocephalides felis*),
 - the treatment of lice infestation (*Trichodectes canis*),
 - the treatment of ear mite infestation (*Otodectes cynotis*), sarcoptic mange infestation (*Sarcoptes scabiei* var. *canis*) and demodicosis (*Demodex canis*),
 - the prevention of heartworm disease (L3 and L4 larvae of *Dirofilaria immitis*),
 - the treatment of circulating microfilariae infestation (*Dirofilaria immitis*),
 - the treatment of subcutaneous dirofilariasis (adults of *Dirofilaria repens*),
 - the prevention of subcutaneous dirofilariasis (L3 larvae of *Dirofilaria repens*),
 - the reduction of circulating microfilariae (*Dirofilaria repens*),
 - the prevention of angiostrongylosis (L4 larvae and immature adults of *Angiostrongylus vasorum*),
 - the treatment of *Angiostrongylus vasorum* and *Crenosoma vulpis* infestations,
 - the prevention of spirocerosis (*Spirocerca lupi*),
 - the treatment of *Eucoleus* (syn. *Capillaria*) *boehmi* infestation (adults),
 - the treatment of the eye worm *Thelazia callipaeda* infestation (adults),
 - the treatment of gastrointestinal nematode infestation (L4 larvae, immature adults and adults of *Toxocara canis*, *Ancylostoma caninum* and *Uncinaria stenocephala*, adults of *Toxascaris leonina* and *Trichuris vulpis*).
- The product can be administered as part of the treatment of flea-induced allergic dermatitis (FAD).

5. Contraindications

Do not use in kittens under 7 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 with heartworm disease classified as class 4 as the safety of the product has not been evaluated for this group of animals.

For cats, the corresponding product "MOXAMID for cats" (0.4 or 0.8 ml), which contains 100 mg/ml imidacloprid and 10 mg/ml moxidectin, must be used.

For ferrets: Do not use MOXAMID for dogs. Use only „MOXAMID for small cats and ferrets (0.4 ml)“.

Do not use in canaries.

6. Special warnings

Brief contact of the animal with water once or twice between two administrations of the product 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.

The use of the product should be based on the confirmed diagnosis of the simultaneous occurrence of mixed infection (or risk of infection, where prevention applies) (see also sections 4 and 8).

The effect against *Dirofilaria repens* adults has not been tested in field conditions.

Parasite resistance to any particular class of anthelmintics may develop following frequent, repeated use of an anthelmintic of that class. Excessive use of antiparasitics, or use contrary to the instructions given in the SPC, may increase resistance through selection pressure and lead to reduced efficacy.

The decision to use the product should be based on confirmation of the parasite species and the associated burden or risk of infestation for each individual animal, taking into account available epidemiological data.

Special precautions for safe use in the target species:

The treatment of animal weighing less than 1 kg should be based on a benefit-risk assessment.

There is limited experience on the use of the product in sick and debilitated animals, thus the product should only be used based on a benefit-risk assessment for these animals.

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

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

Consider carefully the correct application method described in section 8, especially that the product should be applied to the specified site in order to minimise the risk for the animal to lick the product.

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

Animals should be prevented from licking the administration sites.

This product contains moxidectin (a macrocyclic lactone), therefore special care should be taken with Collie or Old English Sheep dogs and related breeds or crossbreeds, to correctly administer the product as described under section with information on proper administration; in particular, oral uptake by the Collie or Old English Sheep dogs and related breeds or crossbreeds should be prevented.

The safety of the product has only been evaluated in dogs classified as either Class 1 or 2 for heartworm disease in laboratory studies and in a few Class 3 dogs in a field study. Therefore the use in dogs with obvious or severe symptoms of the disease should be based on a careful benefit-risk assessment by the treating veterinarian.

Although experimental overdose studies have shown that the product may be safely administered to dogs infected with adult heartworms, it has no therapeutic effect against adult *Dirofilaria immitis*. It is therefore recommended that all dogs 6 months of age or more, living in areas endemic for heartworm, should be tested for existing adult heartworm infection before being treated with the product. At the discretion of the veterinarian, infected dogs should be treated with an adulticide to remove adult heartworms. The safety of MOXAMID has not been evaluated when administered on the same day as an adulticide.

Imidacloprid is toxic for birds, especially canaries.

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

People with known hypersensitivity to benzyl alcohol, imidacloprid or moxidectin should administer the veterinary

medicinal product with caution. 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 product may cause respiratory irritation in sensitive individuals.

Avoid contact with skin, eyes and mouth.

In case of accidental skin contact, wash immediately with soap and water.

In case of accidental contact with eyes, rinse thoroughly with water. If skin or eye irritation persists, or in case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

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

Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

Special precautions for the protection of the environment:

MOXAMID must not contaminate surface waters as it has harmful effects on aquatic organisms. Dogs should not swim in water for 4 days after treatment.

Other precautions:

The solvent present in the veterinary medicinal product may stain or damage certain materials including leather, fabrics, plastics and polished 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. Therefore, the use of the product is not recommended in animals intended for breeding or during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

During treatment with MOXAMID no other antiparasitic macrocyclic lactone should be administered.

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

The safety of MOXAMID has not been evaluated when administered on the same day as an adulticide to eliminate heartworm adults has not been evaluated.

7. Adverse events

Dogs:

Common	Cough, rapid breathing, shortness of breath ¹
(1 to 10 animals / 100 animals treated):	vomiting, diarrhea, loss of appetite ¹ lethargy ¹
Rare	vomiting
(1 to 10 animals / 10.000 animals treated):	
Very rare	local allergic reaction (increased itching, shedding, greasy coat, redness) ²
(≤ 1 animal / 10.000 animals treated, including isolated reports):	neurological signs (ataxia, muscle tremor) ³ behavioural changes (lethargy, restlessness, loss of appetite) ⁴
Frequency not known	itching ⁵
(cannot be determined from available data)	salivation ⁶

¹ These adverse effects were observed in cardiac heartworm positive dogs with microfilaremia in a field study

² These symptoms disappear, no further treatment is necessary.

³ Most of them are transitory.

⁴ Behavioural changes are temporary and caused by local irritation.

⁵ Transitory.

⁶ After licking the administration site immediately after treatment. It is not a sign of poisoning and disappears on its own after a few minutes without the need for treatment.

Overdose:

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

Five times the recommended minimum dose applied at weekly intervals for 17 weeks was investigated in dogs aged over 6 months and tolerated with no evidence of adverse effects or undesirable clinical signs.

The product was administered to puppies at 5 times the recommended dose, every 2 weeks for 6 treatments, and no serious clinical signs occurred. Transient mydriasis, salivation, vomiting and accelerated breathing were observed.

After accidental oral ingestion or overdose, neurological signs (most of which are transient) such as ataxia, generalised convulsions, ocular signs (dilated pupils, little pupillary reflex, nystagmus), abnormal respiration, salivation and vomiting may occur in very rare cases.

Ivermectin-sensitive Collie dogs tolerated up to 5 times the recommended dose repeated at monthly intervals without any adverse effects, but the safety of application at weekly intervals has not been investigated in ivermectin-sensitive Collie dogs. When 40% of a single dose was given orally, severe neurological signs were observed. Oral administration of 10% of the recommended dose produced no adverse effects. Dogs infected with adult heartworms tolerated up to 5 times the recommended dose, every 2 weeks for 3 treatments, without any adverse effects.

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.

Special restrictions for use and special conditions for use:

Not applicable.

Major incompatibilities:

Not known.

Dimensions (mm):
Colours:
Prepared by:
Date:

A5 (148 × 210 mm) duplex printing
black
Hanáková
19. 04. 2024

Approved by:

Date:

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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

Institute for State Control of Veterinary Biologicals and Medicines
Hudcova 232/56a
621 00 Brno
Mail: adr@uskvbl.cz
Web: <http://www.uskvbl.cz/cs/farmakovigilance>

8. Dosage for each species, routes and method of administration
Spot-on use. For external use only.

The recommended minimum doses are 10 mg/kg body weight imidacloprid and 2.5 mg/kg body weight moxidectin, equivalent to 0.1 ml/kg body weight MOXAMID for dogs.
The treatment schedule should be based on individual veterinary diagnosis and on the local epidemiological situation.

Weight of dog [kg]	Tube size to be used	Volume [ml]	Imidacloprid [mg/kg bw]	Moxidectin [mg/kg bw]
≤ 4 kg	MOXAMID for small dogs	0.4	minimum 10	minimum 2.5

Treatment and prevention of flea infestation (*Ctenocephalides felis*)
One treatment prevents flea infestation for 4 weeks. Existing flea pupae in the environment may hatch 6 weeks or later from the start of treatment depending on climatic conditions.
Therefore, it is necessary to combine MOXAMID treatment with environmental treatment to interrupt the flea development cycle. This combination can accelerate the reduction in the household flea population. The product should be administered at monthly intervals when used as part of the treatment of flea allergy dermatitis.

Treatment of lice infestation (*Trichodectes canis*)
Administer a single dose of the product. After 30 days, a veterinary examination is recommended as some animals require a second administration.

Treatment of ear mite infestation (*Otodectes cynotis*)
Administer a single dose of the product. Dislodged detritus should be gently removed from the external ear canal with each administration. After 30 days, a veterinary examination is recommended as some animals require a second administration. Do not apply directly to the ear canal.

Treatment of sarcoptic mange (*Sarcoptes scabiei* var. *canis*)
Administer twice a single dose of the product. Second administration 4 weeks later.

Treatment of demodicosis (*Demodex canis*)
Administration of one dose of the product every 4 weeks for 2 to 4 months is effective against *Demodex canis* and leads to a noticeable improvement in clinical symptoms, especially in moderate and mild conditions. Particularly severe cases may require longer treatment with more frequent administrations. To achieve the best possible response in these severe cases, MOXAMID may be administered once a week for a longer period of time at the discretion of the veterinarian. In all cases, it is essential that treatment be continued until the results of skin scrapings are negative for at least 2 subsequent months. Treatment of dogs should be discontinued if there is no improvement or decrease in mite counts after 2 months of treatment. Alternative therapy is recommended. Consult your veterinarian.

As demodicosis is a multifactorial disease, it is recommended to also treat associated diseases if possible.

Prevention of heartworm infestation (*D. immitis*)
Dogs living in areas endemic for heartworm, or those which have travelled to endemic areas, may be infected with adult heartworms. Therefore prior to treatment with MOXAMID, the advice provided in section 3.5 should be considered.
To prevent heartworm and subcutaneous heartworm infestation, MOXAMID should be administered once a month during the period when mosquitoes (the intermediate host that transmits *D. immitis* larvae) are active. The product may be administered throughout the year.

The first dose may be given after first possible exposure to mosquitoes, but not later than one month after this exposure. Treatment should continue at regular monthly intervals until 1 month after the last exposure to mosquitoes. It is necessary to administer the product every month on the same day or on the same date to ensure regular treatment. If MOXAMID replaces another product with a preventive effect against heartworms, it must be administered within one month after the last dose of the previous product.

In areas where heartworm infection does not occur, the product can be administered without special measures.

Treatment of cutaneous dirofilariasis (subcutaneous worms) (*Dirofilaria repens*)

To prevent cutaneous heartworm disease, the product must be administered at regular monthly intervals during the time of the year when mosquitoes (the intermediate hosts which carry and transmit larvae of *D. repens*) are active. The product may be administered throughout the year or at least 1 month before the first expected contact with mosquitoes. Treatment should continue at regular monthly intervals until 1 month after the last exposure to mosquitoes. It is recommended to use on the same day or date every month to ensure a routine medical treatment.

Treatment of microfilariae infestation (*D. immitis*)
MOXAMID should be administered once a month for the next two months.

Treatment of subcutaneous dirofilariasis (subcutaneous worms) (adults of *Dirofilaria repens*)
MOXAMID should be administered once a month for the next six months.

Limitation of infestation by circulating microfilariae (subcutaneous worms) (*D. repens*)
Administer the product once a month for the next four months.

Treatment and prevention of Angiostrongylus vasorum infestation

Administer a single dose of the product. After 30 days, a veterinary examination is recommended as some animals require a second administration. In endemic areas, regular administration every month provides prevention against angiostrongylosis and overt infection with *Angiostrongylus vasorum*.

Treatment of Crenosoma vulpis infestation
Administer a single dose of the product.

Prevention of spirocerosis (infestation with *Spirocerca lupi*)
Administer MOXAMID once a month.

Treatment of Eucoleus (syn. Capillaria) boehmi infestation (adults)

Administer the product once a month for two consecutive months. Avoiding autocannibalism between the two treatments is recommended to prevent possible reinfection.

Treatment of the eye worm *Thelazia callipaeda* infestation (adults)
Administer a single dose of the product.
Treatment of nematodiasoses caused by roundworms, hookworms and whipworms (*Toxocara canis*, *Ancylostoma caninum*, *Uncinaria stenocephala*, *Toxascaris leonina* and *Trichuris vulpis*)
In areas with heartworm infestations, monthly treatment can significantly reduce the risk of reinfection with roundworms, hookworms and pinworms. In areas without the occurrence of heartworms, the product can be used as part of a preventive program against fleas and gastrointestinal nematodes. Studies have shown that regular monthly treatments prevent *Uncinaria stenocephala* infection.

9. Advice on correct administration
Hold the tube with the neck upwards and knock the neck repeatedly with your finger. Break off the tip carefully by twisting motion.

With the dog in a standing position, part the fur between the shoulder blades until the skin is visible. Apply to undamaged skin. Place the tip of the tube on the skin and squeeze the tube several times to empty its contents directly onto the skin.

10. Withdrawal periods
Not applicable.

11. Special storage precautions
Keep out of the sight and reach of children.
Store in the original package in order to protect from light and moisture.

This veterinary medicinal product does not require any special temperature storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and box 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.

This veterinary medicinal product must not contaminate watercourses as 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.

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
Paper box contains 1 or 3 single-dose pipettes.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised
September 2023
Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).
Detailed information on this veterinary medicinal product is also available in the national database (<https://www.uskvbl.cz>).

16. Contact details
Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Bioveta, a. s.
Komenského 212/12
683 23 Ivanovice na Hané
Czech Republic
Tel.: +420 517 318 500
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 product.
The product has a persistent action and protects dogs for 4 weeks after a single application against reinfection with *Dirofilaria immitis*, *Dirofilaria repens*, *Angiostrongylus vasorum*.
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 dogs.
Environmental properties: Moxidectin has been classified as persistent, bioaccumulative and toxic in the environment.

