

MOXAMID 80 mg/8 mg spot-on solution for large cats S

1. Name of the veterinary medicinal product

MOXAMID 80 mg/8 mg spot-on solution for large cats S

2. Composition

One pipette (0.8 ml) contains:

Active substances:	
Imidacloprid	80 mg
Moxidectin	8 mg

Excipients:

Butylhydroxytoluene (E 321)	0.8 mg
Benzyl alcohol (E 1519)	658 mg
A clear, colourless to yellowish solution.	

3. Target species

Cats (> 4-8 kg).

4. Indications for use

For cats suffering from, or at risk from, mixed parasitic infections:

- 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*) infestation (adults)
- the prevention of lungworm disease (L3/L4 larvae of *Aelurostrongylus abstrusus*),
- the treatment of the lungworm *Aelurostrongylus abstrusus* disease (adults),
- the treatment of the eye worm *Thelazia callipaeda* infestation (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 administered as part of the treatment of flea-induced allergic dermatitis (FAD).

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

For dogs, the corresponding product "MOXAMID for dogs", which contains 100 mg/ml imidacloprid and 25 mg/ml moxidectin, must be used.

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:

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 9, 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. 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 to check the heartworm status of any cat and ferret aged over 6 months before beginning prophylactic treatment as use of the product in 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 some cats, *Notoedres cati* infestation can be very 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:

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.

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.

Overdose:

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 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.

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.

Special restrictions for use and special conditions for use:

Not applicable.

Major incompatibilities:

Not known.

7. Adverse events

Cats:

Rare	greasy fur ¹ , erythema ¹
(1 to 10 animals / 10.000 animals treated):	vomiting ¹
Very rare	local allergic reaction
(< 1 animal / 10.000 animals treated, including isolated reports):	neurological signs ²
	behavioural changes (lethargy, restlessness, loss of appetite) ³
Frequency not known	itching ⁴
(cannot be determined from available data)	salivation ⁵

¹ These symptoms disappear, no further treatment is necessary.

² Most of them are transitory. If the animal licks the administration site after treatment.

³ Behavioural changes are temporary and caused by local irritation.

⁴ Transitory.

⁵ 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.

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 1.0 mg/kg body weight moxidectin, equivalent to 0.1 ml/kg body weight MOXAMID for cats.

The treatment schedule should be based on individual veterinary diagnosis and on the local epidemiological situation.

Weight of cat [kg]	Tube size to be used	Volume [ml]	Imidacloprid [mg/kg bw]	Moxidectin [mg / kg bw]
> 4-8 kg	MOXAMID for large cats	0.8	10-20	1-2
> 8 kg	A suitable combination of pipettes.			

Dimensions (mm):

Colours:

Prepared by:

Date:

A5 (148 × 210 mm) duplex printing

black

Hanáková

21. 03. 2024

Approved by:

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Date:

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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 ear mite infestation (*Otodectes cynotis*)

Administer a single dose of the product. 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 notoedric mange (*Notoedres cati*)

Administer a single dose of the product.

Treatment of the lungworm *Eucoleus aerophilus* (syn. *Capillaria aerophila*) infestation (adults)

Administer a single dose of the product.

Prevention of *Aelurostrongylus abstrusus*

The product should be administered monthly.

Treatment of *Aelurostrongylus abstrusus*

MOXAMID should be administered monthly for three consecutive months.

Treatment of the eye worm *Thelazia callipaeda* infestation (adults)

Administer a single dose of the product.

Prevention of heartworm infestation (*Dirofilaria immitis*)

Cats 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 6 should be considered.

To prevent heartworm infestation, MOXAMID should be administered once a month during the period when mosquitoes (the intermediate host that transmits heartworm 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 more 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 nematode infections caused by roundworms and hookworms (*Toxocara cati* and *Ancylostoma tubaeforme*)

In areas with heartworm infestations, monthly treatment can significantly reduce the risk of reinfection with roundworms and hookworms. In areas without the occurrence of heartworms, the product can be used as part of a preventive program against fleas and gastrointestinal nematodes.

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.

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 several times to empty its contents directly onto the skin. Application to the base of the skull minimises the risk of the product being licked by the animal. Apply only to undamaged 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 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.

Environmental properties: Moxidectin has been classified as persistent, bioaccumulative and toxic in the environment.

