1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxiclear 80 mg + 8 mg spot-on solution for large cats.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.8 ml pipette contains:

Active substances:
Imidacloprid 80 mg
Moxidectin 8 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxytoluene (E 321)	0.8 mg
Benzyl Alcohol	to 0.8 ml
Propylene carbonate	

A clear colourless to yellow solution with light opalescence.

3. CLINICAL INFORMATION

3.1 Target species

Cats (>4-8 kg).

3.2 Indications for use for each target species

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 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).

3.3 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 this veterinary medicinal product for large cats (0.8 ml) or the corresponding veterinary medicinal product for dogs (any size). Only the corresponding veterinary medicinal product for small cats and ferrets (0.4 ml) which contains 40 mg/ml imidacloprid and 4 mg/ml moxidectin, must be used.
For dogs, the corresponding veterinary medicinal product for dogs, which contains 100 mg/ml imidacloprid and 25 mg/ml moxidectin, must be used.
Do not use on canaries.

3.4 Special warnings

The veterinary medicinal 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 veterinary medicinal product. However, frequent shampooing or immersion of the animal in water after treatment may reduce the efficacy of the veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product should be based on the confirmed diagnosis of mixed infection (or risk of infection, where prevention applies) at the same time (see also sections 3.2 and 3.9).

3.5 Special precautions for use

Special precautions for safe use in the target species:

The treatment of cats weighing less than 1 kg and ferrets weighing less than 0.8 kg should be based on a risk-benefit 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 risk-benefit assessment for these animals.

Care should be taken that the content of the pipette or the applied dose does 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 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 and ferret aged over 6 months, before beginning prophylactic treatment, as use of the veterinary medicinal product on cats or ferrets which have adult heartworms may cause serious adverse events, 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.

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.
If the veterinary medicinal product accidentally gets into eyes, they should be thoroughly flushed with water.
In case of accidental spillage onto skin, wash off immediately with soap and 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.
Do not ingest. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
People with 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 veterinary medicinal product may cause respiratory irritation in sensitive individuals.
In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.
After application do not stroke or groom animals until the application site is dry.
Treated animals should not be handled until the application site is dry, and children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children.

Special precautions for the protection of the environment:

Not applicable.

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.

3.6 Adverse events

Cats:

Rare (1 to 10 animals / 10,000 animals treated):	Application site greasy fur[1], Erythema[1], Vomiting[1] Hypersensitivity reaction (local)
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Pruritus[2] Neurological signs[3] Hypersalivation[4], Behavioural disorders (e.g. agitation)[5], Lethargy[5], Inappetence[5])

[1] Disappears without further treatment.
[2] In cats. Transient.
[3] If the animal licks the application site after treatment. Mostly transient.
[4] If the animal licks the application site immediately after treatment. Not a sign of intoxication; disappears within minutes. Correct application will minimise licking of the application site.
[5] Caused by a sensation at the application site.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder

or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 Interaction with other medicinal products and other forms of interaction

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.

3.9 Administration routes and dosage

Dosage schedule for cats:

Spot-on use.

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.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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

Weight of cat	Pipette size to be used	Volume	Imidacloprid [mg/kg bw]	Moxidectin [mg/kg bw]
≤ 4 kg	Veterinary medicinal product for small cats	0.4 ml	minimum of 10	minimum of 1
> 4 ≤ 8 kg	Veterinary medicinal product for large cats	0.8 ml	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 treatment of the veterinary medicinal product 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.

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 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. 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 medication.

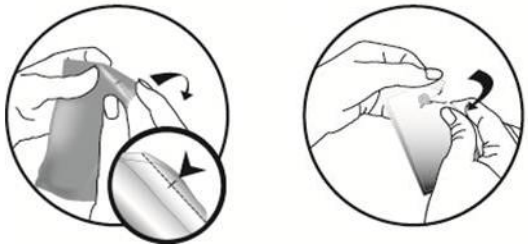
In non-endemic areas there should be no risk of cats having heartworm. Therefore, they can be treated without special precautions.

Roundworm and hookworm treatment *(Toxocara cati* and *Ancylostoma tubaeforme)*

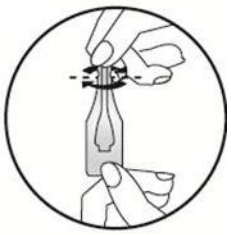
In areas endemic for heartworm, monthly treatment may significantly reduce the risk of re-infection caused by the respective roundworms and hookworms. In areas non-endemic for heartworm, the veterinary medicinal product can be used as part of a seasonal prevention programme against fleas and gastrointestinal nematodes.

Method of administration

For external use only. Do not remove the pipette from the sachet until ready to use.
Remove the pipette from the outer sachet using scissors or fold along diagonal line to expose nick; tear back at nick.



Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Twist or snap back the tip.



Part the coat on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot. 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Up to 10 times the recommended dose was tolerated in cats with no evidence of adverse events 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.

The veterinary medicinal product was administered to ferrets at 5 times the recommended dose, every 2 weeks for 4 treatments, and there was no evidence of adverse events 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP54AB52.

4.2 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 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.

4.3 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 and is slowly eliminated from the plasma as manifested by detectable moxidectin concentrations in plasma throughout the treatment interval of one month.

Environmental properties

See section 5.5.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

Do not store above 25 °C.
Store in the original package in order to protect from light and moisture.

5.4 Nature and composition of immediate packaging

0.8 ml clear pipette with a film composed of 3 layers: a polypropylene/COC, solvent free lacquer laminate and a copolymer of polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachet composed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.

Package Sizes
Pipettes are presented in cardboard boxes containing 1, 2, 3, 4, 6, 9, 12, 21 or 42 pipettes.
Each pipette is individually sealed in a foil sachet.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

The veterinary medicinal product should not enter water courses as imidacloprid and 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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/139/002

8. DATE OF FIRST AUTHORISATION

24/11/2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

14/02/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).