PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton of 1, 2, 3, 4, 6, 9, 12, 21 and 42 pipette(s) – 0.4 ml pipettes}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxiclear 40 mg + 4 mg spot-on solution for small cats and ferrets

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.4 ml pipette contains:

Imidacloprid 40 mg
Moxidectin 4 mg

3. PACKAGE SIZE

1 x 0.4 ml
2 x 0.4 ml
3 x 0.4 ml
4 x 0.4 ml
6 x 0.4 ml
9 x 0.4 ml
12 x 0.4 ml
21 x 0.4 ml
42 x 0.4 ml

4. TARGET SPECIES

Cats (≤ 4 kg) and ferrets.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For external use only.
Spot-on use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Ltd

14. MARKETING AUTHORISATION NUMBER

Vm 02000/4435

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Sachet for 0.4 ml pipette}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxiclear 40 mg + 4 mg spot-on solution for small cats and ferrets

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.4 ml pipette contains:
Imidacloprid 40 mg
Moxidectin 4 mg

3. TARGET SPECIES

Cats (≤ 4 kg) and ferrets.

4. ROUTES OF ADMINISTRATION

For external use only.
Spot-on use
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

Store in the original package in order to protect from light and moisture.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {0.4 ml pipette}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxiclear

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

40mg/4mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Moxiclear 40 mg + 4 mg spot-on solution for small cats and ferrets

2. Composition

Each 0.4 ml pipette contains:

Active substances:

Imidacloprid	40 mg
Moxidectin	4 mg

Excipients:

Butylhydroxytoluene (E 321)	0.4 mg
Benzyl Alcohol	to 0.4 ml

A clear colourless to yellow solution with light opalescence.

3. Target species

Cats (≤ 4 kg) and ferrets.

4. Indications for use

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* (roundworm) and *Ancylostoma tubaeforme* (hookworm)).

The veterinary medicinal product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

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

- For the treatment and prevention of flea infestation (*Ctenocephalides felis*),
- the prevention of heartworm disease (L3 and L4 larvae of *Dirofilaria immitis*).

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

6. Special warnings

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 the Section 4 "Indications for use" and Section 8 "Dosage for each species, routes and method of administration" of this package leaflet for additional information).

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 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.

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.
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.
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 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 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.

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.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Laboratory studies with either imidacloprid or moxidectin in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

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.

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.

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.

7. Adverse events

Target Species: Cats, Ferrets.

Rare (1 to 10 animals / 10,000 animals treated):	Application site greasy fur[1], Erythema (redness)[1], Vomiting[1] Hypersensitivity reaction (local)
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Pruritus (itching) [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 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:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Spot-on use.

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 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 the section 6 “Special warnings” 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 veterinary medicinal 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.

Dosage schedule for ferrets:

One pipette of the veterinary medicinal product for small cats (0.4 ml) should be administered per animal. Do not exceed the recommended dose.
The treatment schedule should be based on the local epidemiological situation.

Flea treatment and prevention (Ctenocephalides felis)
One treatment prevents future flea infestation for 3 weeks. Under heavy flea pressure it may be necessary to repeat administration after 2 weeks.

Heartworm prevention (Dirofilaria immitis)

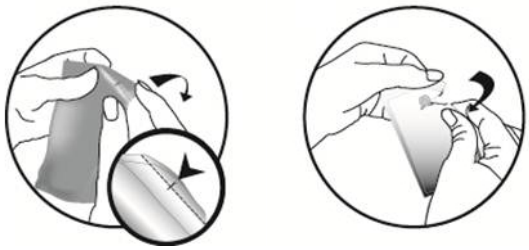
Ferrets in areas endemic for heartworm, or those which have travelled to endemic areas, may be infected with adult heartworms. Therefore prior to treatment with the veterinary medicinal product, the advice provided in the section 6 “Special warnings” should be considered.

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

9. Advice on correct 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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 °C.
Store in the original package in order to protect from light and moisture.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton 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.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon 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

Vm 02000/4435

0.4 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.

Pipettes are presented in cartons 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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Norbrook Laboratories Limited,
Station Works,
Newry,
Co. Down,
BT35 6JP,
United Kingdom
Tel: +44 (0)28 3026 4435
E-mail: phvdept@norbrook.co.uk

Manufacturer responsible for batch release:
Norbrook Laboratories Limited,
Station Works,
Newry,
Co. Down,
BT35 6JP,
United Kingdom

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Distributed By:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ, Co Down
Northern Ireland

Gavin Hall

Approved: 19 June 2025