

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton of 1, 2, 3, 4, 6, 9, 12, 21 and 42 pipette(s) – **0.8 ml pipettes**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxiclear 80 mg + 8 mg spot-on solution for large cats
Imidacloprid, moxidectin

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.8 ml pipette contains:

Active substances:
Imidacloprid 80 mg
Moxidectin 8 mg

3. PHARMACEUTICAL FORM

Spot-On Solution.

4. PACKAGE SIZE

1 x 0.8 ml
2 x 0.8 ml
3 x 0.8 ml
4 x 0.8 ml
6 x 0.8 ml
9 x 0.8 ml
12 x 0.8 ml
21 x 0.8 ml
42 x 0.8 ml

5. TARGET SPECIES

For large cats weighing between 4 kg and 8 kg

6. INDICATION(S)

Indication to be included only for medicinal products not subject to medical prescription.

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 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 used as part of a treatment strategy for flea allergy dermatitis (FAD).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.

Spot-on use. Do not remove the pipette from the sachet until ready to use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read the package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

POM-V

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Ltd
Station Works
Newry
Co. Down
BT35 6JP

16. MARKETING AUTHORISATION NUMBER(S)

VM 02000/4436

17. MANUFACTURER'S BATCH NUMBER

BN

- ✓ Flea
- ✓ Flea larvae
- ✓ Hookworm
- ✓ Roundworm
- ✓ Heartworm
- ✓ Otodectes
- ✓ Notoedres

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachet for 0.8 ml pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxiclear 80 mg + 8 mg spot-on solution for large cats
Imidacloprid, moxidectin

2. QUANTITY OF ACTIVE SUBSTANCE(S)

One 0.8 ml pipette contains:
Imidacloprid 80 mg
Moxidectin 8 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

0.8 ml

4. ROUTE(S) OF ADMINISTRATION

For external use only.
Spot-on use
<Pictogram of a spot-on pipette>

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {mm/yyyy}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

<Pictogram of a cat>

9. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited



MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

0.8 ml pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxiclear

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook

3. EXPIRY DATE

EXP {mm/yyyy}

4. BATCH NUMBER

XXXX XXX

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

<Pictogram of a cat>

6. PHARMACEUTICAL FORM

<Pictogram of a spot-on pipette>

7. VOLUME

0.8 ml

8. TARGET ANIMAL WEIGHT RANGE

> 4 ≤ 8 kg

9. QUANTITY OF ACTIVE SUBSTANCE(S)

80mg/8mg



PACKAGE LEAFLET

PACKAGE LEAFLET:

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

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
AND OF THE MANUFACTURING AUTHORISATION HOLDER
RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder

(EU) Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK) Norbrook Laboratories Limited,
Station Works,
Newry,
Co. Down,
BT35 6JP,
United Kingdom

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxiclear 80 mg + 8 mg spot-on solution for large cats
Imidacloprid, moxidectin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Each 0.8ml pipette contains:

Active substances:

Imidacloprid	80 mg
Moxidectin	8 mg

Excipients:

Butylhydroxytoluene (E 321)	0.8 mg
Benzyl Alcohol	to 0.8 ml

A clear colourless to yellow solution with light opalescence.

4. INDICATIONS

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 product can be used as part of a treatment strategy for flea allergy 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:

For ferrets: Do not use Moxiclear for large cats (0.8 ml) or Moxiclear for dogs (any size).

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

Do not use on canaries.

6. ADVERSE REACTIONS

Use of the product may result in transient pruritus in cats. On rare occasions greasy fur, erythema and vomiting can occur. These signs disappear without further treatment. The product may, in rare cases, cause local hypersensitivity reactions. If the animal licks the application site after treatment, neurological signs (most of which are transient) such as ataxia, generalized tremors, ocular signs (dilated pupils, little pupillary reflex, nystagmus), abnormal respiration, salivation and vomiting may be observed in very rare cases.

The product tastes bitter. Salivation may occasionally occur if the animal licks the application site immediately after treatment. This is not a sign of intoxication and disappears within some minutes without treatment. Correct application will minimise licking of the application site.

The product may in very rare cases cause at the application site a sensation resulting in transient behavioural changes such as lethargy, agitation, and inappetence.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 product.

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	Moxiclear for small cats	0.4 ml	minimum of 10	minimum of 1
> 4 ≤ 8 kg	Moxiclear 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 with the 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 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 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 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 product, the advice provided in the section “SPECIAL WARNING(S)” should be considered.

For prevention of heartworm disease, the 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 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 product must be given within 1 month of the last dose of the former medication.

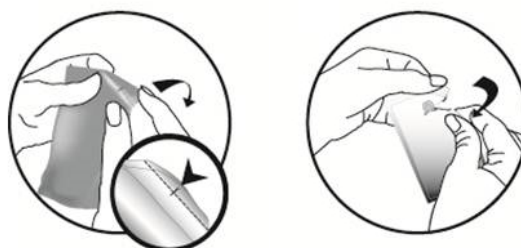
In non-endemic areas there should be no risk of cats having heartworm. Therefore they can be treated without special precautions.

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 product can be used as part of a seasonal prevention programme against fleas and gastrointestinal nematodes.

9. ADVICE ON CORRECT ADMINISTRATION

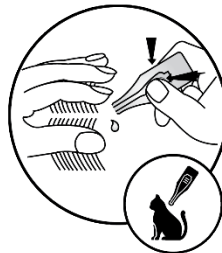
For external use only. Do not remove the pipette from the sachet until ready to use. Remove the pipette from the outer sachet using scissors or fold along diagonal line to expose nick; tear back at nick.



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 product. Apply only to undamaged skin.



10. WITHDRAWAL PERIOD

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}.

12. SPECIAL WARNINGS

For Animal Treatment Only.

Special warnings for each target species:

The 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 product. However, frequent shampooing or immersion of the animal in water after treatment may reduce the efficacy of the

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 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 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 "INDICATIONS" and "DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION" sections of this package leaflet for additional information).

Special precautions for use in animals:

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 product in sick and debilitated animals, thus the 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 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 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 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.

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

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

People with known hypersensitivity to benzyl alcohol, imidacloprid or moxidectin should administer the product with caution. In very rare cases the 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. If the product accidentally gets into eyes, they should be thoroughly flushed with water.

If skin or eye symptoms persist, or the 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.

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.

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.

The solvent in the 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. 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.

Interaction with other medicinal products and other forms of interaction:

During treatment with Moxiclear no other antiparasitic macrocyclic lactone should be administered. No interactions between Moxiclear and routinely used veterinary medicinal products or medical or surgical procedures have been observed.

Overdose (symptoms, emergency procedures, antidotes):

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 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 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Moxiclear should not enter water courses as this may be dangerous for fish and other aquatic organisms. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2019

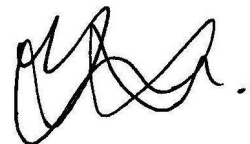
15. OTHER INFORMATION

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.

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.

Pipettes are presented in cartons of 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



Approved: 29 July 2022