PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Outer carton, pack size of 3, 6 or 21 pipettes.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Endectrid 80 mg + 8 mg spot-on solution for large cats
Imidacloprid, Moxidectin

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.8 ml pipette contains 80.0 mg imidacloprid and 8.0 mg moxidectin as activesubstances

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

3 pipettes
6 pipettes
21 pipettes

5. TARGET SPECIES

For large cats weighing between 4 kg and 8 kg.

6. INDICATION(S)

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 treatment of the lungworm *Eucoleus aerophilus* (syn. *Capillaria aerophila*)(adults),
- the prevention of lungworm disease (L3/L4 larvae of *Aelurostrongylus abstrusus*),
- the treatment of the lungworm *Aelurostrongylus abstrusus* (adults),
- the treatment of the lungworm Troglostrongylus brevior (adults),
- the treatment of the eye worm *Thelazia callipaeda* (adults),
- the prevention of heartworm disease (L3 and L4 larvae of *Dirofilaria immitis*),
- the treatment of infections with gastrointestinal nematodes (L4 larvae, immatureadults 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.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Do not use in kittens under 9 weeks of age. Consult your veterinarian before using theproduct on pregnant or lactating cats, or on sick or debilitated cats, or on cats under 1kg.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only - to be supplied only on veterinary prescription.

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

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood
Business ParkHook
RG27 9XA
United Kingdom

Manufacturer responsible for batch release:KVP Pharma + Veterinär Produkte GmbH Projensdorfer Str. 324, 24106 Kiel Germany

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4135

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

Local Representative:
MiPet
Owen Road
Diss
Norfolk
IP22 4ER

Tel: 01379 658042
products@cvsvets.com

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Pipette label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Endectrid spot-on for large cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Imidacloprid 80.0 mg, Moxidectin 8.0 mg

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

0.8 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Endectrid spot-on for large cats(> 4–8 kg)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET:

Endectrid 40 mg + 4 mg spot-on solution for small cats and ferrets
Endectrid 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 RESPONSIBLEFOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park Hook
RG27 9XA
United Kingdom

Manufacturer responsible for batch release:
KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324, 24106 Kiel
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Endectrid 40 mg + 4 mg spot-on solution for small cats and ferrets
Endectrid 80 mg + 8 mg spot-on solution for large cats
Imidacloprid, Moxidectin

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

Each 0.4 ml / 0.8 ml pipette contains:

Active substance(s):

Imidacloprid	40.0 mg / 80.0 mg
Moxidectin	4.0 mg / 8.0 mg

Excipient(s):

Butylhydroxytoluene (E 321)	0.4 mg / 0.8 mg
Benzyl alcohol	328.6 mg / 657.2 mg

A clear yellow to brownish spot-on solution.

4. INDICATION(S)

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 treatment of the lungworm *Eucoleus aerophilus* (syn. *Capillaria aerophila*)(adults),
- the prevention of lungworm disease (L3/L4 larvae of *Aelurostrongylus abstrusus*),
- the treatment of the lungworm *Aelurostrongylus abstrusus* (adults),
- the treatment of the lungworm Troglostrongylus brevior (adults),
- the treatment of the eye worm *Thelazia callipaeda* (adults),
- the prevention of heartworm disease (L3 and L4 larvae of *Dirofilaria immitis*),
- the treatment of infections with gastrointestinal nematodes (L4 larvae, immatureadults and adults of *Toxocara cati* and *Ancylostoma tubaeforme*).

The 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 known hypersensitivity to the active substances or to any of theexcipients.
For ferrets: Do not use Endectrid for large cats (0.8 ml) or Endectrid for dogs (any size).

For dogs, the corresponding “Endectrid for dogs” 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, generalised 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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cats, ferrets

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OFADMINISTRATION

For external use only.

To prevent licking, apply topically to the skin restricting the area of application to theanimal's neck at the base of the skull.

Dosage schedule for cats

The recommended minimum doses are 10 mg/kg bodyweight imidacloprid and 1.0mg/kg bodyweight moxidectin, equivalent to 0.1 ml of the product per kg bodyweight.

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

Weight of cat [kg]	Pipette size to be used	Volume [ml]	Imidacloprid [mg/kg bw]	Moxidectin [mg/kg bw]
≤ 4 kg	Endectrid for small cats and ferrets	0.4	minimum of 10	minimum of 1
> 4–8 kg	Endectrid for large cats	0.8	10–20	1–2
> 8 kg	appropriate combination of pipettes			

Flea treatment and prevention (*Ctenocephalides felis*)

One treatment prevents further flea infestation for 4 weeks. Pre-existing pupae in the environment may continue to emerge for 6 weeks or longer after treatment is initiateddepending upon climatic conditions. Therefore, it may be necessary to combine the treatment with this product with environmental treatments aimed at breaking the flea life cycle in the surroundings. This can result in more rapid reductions in the householdflea 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.

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

A single dose of the product should be administered.

Prevention of Aelurostrongylus abstrusus

The product should be administered monthly.

Treatment of Aelurostrongylus abstrusus

The product should be administered monthly for three consecutive months.

Treatment of Troglostrongylus brevior (adults)

Endectrid should be administered monthly for two consecutive months.

Treatment of the eye worm Thelazia callipaeda (adults)

A single dose of the product should be administered.

Heartworm prevention (Dirofilaria immitis)

Cats in endemic areas, or those which have travelled to endemic areas, may be infected with adult heartworms. Therefore prior to treatment with this 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. The 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 anotherheartworm preventative product in a heartworm prevention programme, the firsttreatment with this product must be given within 1 month of the last dose of the formermedication.

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

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.

Dosage schedule for ferrets:

One 0.4 ml pipette of this product should be administered per animal. Do not exceedthe 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 pressureit may be necessary to repeat administration after 2 weeks.

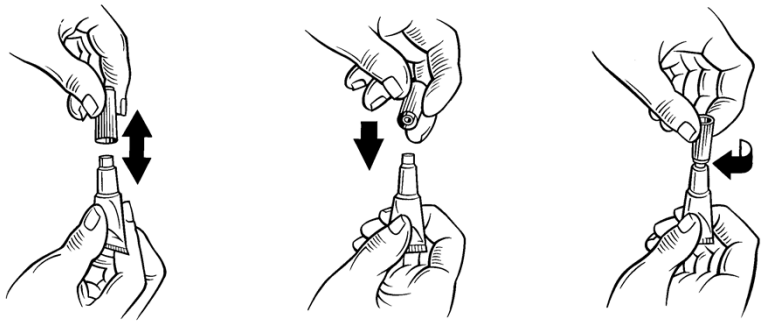
Heartworm prevention (Dirofilaria immitis)

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 this product, the advice provided in the section “SPECIAL WARNING(S)” should beconsidered.

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.
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

Remove one pipette from the package. Then hold the pipette in an upright position, and twist and pull off cap. Reverse the cap and use it to twist and remove the seal from the pipette, as shown.



Part the fur on the animal's neck at the base of the skull until the skin is visible. Place the tip of the pipette on the skin and squeeze the pipette firmly several times to empty its contents directly onto the skin. 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.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date stated on the

labeland carton. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:

The product's efficacy has not been tested in ferrets weighing over 2 kg and thereforethe 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 sections 4 and 8).

Special precautions for use in animals:

Treatment of cats weighing less than 1 kg and ferrets weighing less than 0.8 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 mouth of the recipient and/or other animals. Consider carefully thecorrect application method described in section 9, especially that the product should be applied at the base of the skull in order to minimise the risk for the animal to lick theproduct. 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 isdry.

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, prior to beginning of prophylactic treatment, as

use of the product on cats or ferrets which have adult heartworm 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.
In order to prevent children getting access to pipettes, keep the pipette in the originalpackaging until ready for use and dispose of used pipettes immediately.
Wash hands thoroughly after use.
After application do not stroke or groom animals until the application site is dry. This may be ensured by treating animals in the evening. Do not allow recently treatedanimals to sleep with owners, especially children.
In case of accidental spillage onto skin, wash off immediately with soap and water. People with a known hypersensitivity to benzyl alcohol, imidacloprid or moxidectinshould administer the product with caution. In very rare cases the product may causeskin sensitisation or transient skin reactions (for example numbness, irritation orburning/tingling sensation).
In very rare case 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 if the product is accidentally swallowed, seek medicaladvice immediately and show the package leaflet or the label to the physician.

Other precautions

The solvent in this 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 in the target species. Therefore, the use of the product is notrecommended in animals intended for breeding or during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

During treatment with this veterinary medicinal product no other antiparasitic macrocyclic lactone should be administered.

No interactions between this veterinary medicinal product and routinely used veterinarymedicinal 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.

Incompatibilities:

None known.

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

Dispose of any unused veterinary medicinal product, or waste materials, in accordance with local requirements (i.e. via household waste). Medicines should not be disposed of via wastewater.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2023

15. OTHER INFORMATION

Imidacloprid is effective against larval flea stages and adult fleas. Flea larvae in thepet’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.

Pack sizes: 0.4 ml and 0.8 ml per pipette.
Blister packs containing 3, 6 or 21 pipettes.

Not all pack sizes may be marketed.

0.4 ml: Vm 00879/4133
0.8 ml: Vm 00879/4135

POM-V

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

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Diss
Norfolk
IP22 4ER

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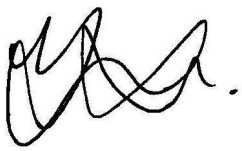
products@cvsvets.com



Approved: 13 February 2023