SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectra Felis 423 mg/42.3 mg spot-on solution for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Each 0.9 ml spot-on applicator delivers:

Dinotefuran……..	423 mg
Pyriproxyfen……	42.3 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.
Colourless to pale yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

Treatment and prevention of flea infestations (*Ctenocephalides felis*) on cats.
One application prevents flea infestation for one month. It also prevents the multiplication of fleas by inhibiting flea emergence in the environment of the cat for 3 months.

4.3 Contraindications

Do not use in cats or kittens weighing less than 0.6 kg.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings for each target species

All cats within the household should be treated. Dogs in the household should only be treated with a veterinary medicinal product authorised for use in that species.

Fleas can infest the cat's basket, bedding and regular resting areas such as carpets and soft furnishings. In case of massive flea infestation and at the beginning of the control measures, these areas should be treated with a suitable insecticide and then vacuumed regularly.
The impact of shampooing on the efficacy of the veterinary medicinal product has not been evaluated.

In case of suspicion of dermatitis (itch and skin irritation), seek for veterinary advice.

4.5 Special precautions for use

Special precautions for use in animals

The safety of the product has not been established in cats younger than 7 weeks or weighing less than 0.6 kg (see section 4.3).

After accidental ingestion of the product, transient reactions such as salivation, abnormal faeces and emesis may occur, however these should resolve without treatment within 4 hours.

Care should be taken to apply the dose to an area where the animal cannot lick it off (see section 4.9), and to ensure that animals do not groom each other immediately following treatment.
Care should be taken to ensure that the contents of the spot-on applicator, or the applied dose, do not come into contact with the eyes of the cat to be treated and/or any other animals.

No studies have been performed in sick or convalescent cats, therefore use in these cats should be based on the benefit-risk assessment of a veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to dinotefuran, pyriproxyfen or dimethyl sulfoxide should avoid contact with this veterinary medicinal product.

The veterinary medicinal product is irritating to the eyes and skin.

To avoid adverse reactions:
- Wash hands thoroughly and immediately after use.
- Avoid contact with the skin, eyes or mouth.
- In case of accidental spillage onto skin, wash off immediately with soap and water.

- If the veterinary medicinal product accidentally gets into the eyes, they should be rinsed with water immediately, with the eyelids open, and for a sufficient length of time.
- Treated animals must not be handled for at least eight hours after application of the product. It is therefore recommended to treat the animal in the evening.
- Treated animals should not be allowed to sleep with their owners, especially children, on the day of treatment.
- Used applicators should be disposed of immediately and not left within the sight or reach of children.

If skin or if eye irritation persists, or in case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Slight scales, transient erythema and alopecia can be observed in rare cases, which usually disappear spontaneously without treatment.
Transient neurological signs such as muscle tremors or lethargy may occur very rarely and in particular after application site licking.
Transient cosmetic effects such as wet hair and a white dry residue may occur at the application site very rarely and may persist up to 7 days; however, these effects are usually not noticeable after 48 hours. These changes do not affect the safety or the efficacy of the veterinary medicinal product.
Other application site disorders such as erythema, pruritus, lesions and inflammation may occur very rarely.
Hyperactivity and tachypnoea may occur very rarely.

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).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in adult female cats.
Use only accordingly to the benefit/risk assessment by the responsible veterinarian.
Laboratory studies with each of the components, dinotefuran or pyriproxyfen, in rats and rabbits have not produced any evidence of maternotoxic, teratogenic or foetotoxic effects.

In rats, dinotefuran has been shown to cross the blood-milk barrier and is excreted in the milk.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Dosage:
The minimum recommended dose is 42.3 mg dinotefuran/kg bodyweight and 4.23 mg pyriproxyfen/kg bodyweight.

The treatment dose range is 42.3 to 705 mg dinotefuran/kg bodyweight (bw) and 4.23 to 70.5 mg pyriproxyfen/kg bodyweight (bw) for cats of 0.6 kg to 10 kg bodyweight.

Method and route of administration:
Spot-on use.

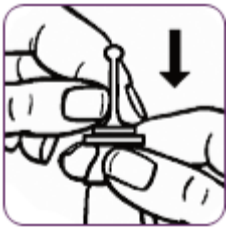
Care should be taken to apply the veterinary medicinal product only onto intact (undamaged) cat's skin.

Treatment schedule:
Following a single administration, the veterinary medicinal product will prevent flea infestation for one month and prevent further flea multiplication by inhibiting flea emergence in the environment of the cat for 3 months. The need to re-treat cats which are likely to be re-infested, and the time interval between such treatments, should be based on an assessment by a veterinarian.

How to apply:
Remove the spot-on applicator from the pack.

Step 1: Hold the applicator upright, placing fingers below the larger disk as shown.

Step 2: With the other hand, press downwards on the smaller disk until the 2 disks meet evenly. This will pierce the seal.



Step 3: The cat should be standing or in a comfortable position for easy application. At the base of cat's head, part the hair until the skin is visible. Apply the veterinary medicinal product slowly with the tip of the applicator on the skin. Avoid superficial application to the cat's hair.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No clinically important adverse reactions were observed in healthy kittens aged 7 weeks or more, topically treated 7 times at 2 week intervals and with up to 4 times the highest recommended dose except transient oedema or dry skin at the application site.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic products, insecticides and repellents, other ectoparasiticides for topical use.
ATCvet code: QP53AX73.

5.1 Pharmacodynamic properties

Dinotefuran is an insecticide. Its structure is derived from the neurotransmitter acetylcholine and it acts on nicotinic acetylcholine receptors of the insect nerve synapse. Once bound to these receptors, the full agonist action of repeated excitatory impulses kills the insect. Insects do not have to ingest dinotefuran, it kills by contact. Dinotefuran has a low affinity for mammalian acetylcholine receptor sites. Fleas are killed by dinotefuran within 2 hours after treatment or infestation.

Pyriproxyfen is a photostable insect growth regulator (IGR). It acts through contact, by mimicking the juvenile hormone which regulates the moulting of insects from one life stage to the next. Pyriproxyfen stops the flea life cycle by both inducing premature oviposition and also suppressing yolk deposition in flea eggs, leading to the production of infertile eggs. Pyriproxyfen also blocks the development of juvenile stages (larvae and early (pharate) pupae) into adult emergence. This prevents infestation within the environment of the treated animal.

5.2 Pharmacokinetic particulars

Following topical application, the two actives rapidly distribute over the body surface of the animal within the first day and were still measurable in different zones of the hair coat one month after treatment.

Dinotefuran and pyriproxyfen are partially absorbed by the cat skin (30% and 12% respectively), but this systemic absorption is not relevant for the clinical efficacy of the product.

In laboratory species, after intra-peritoneal administration, dinotefuran is rapidly eliminated as the unchanged parent molecule mainly via the urine. After oral administration, pyriproxyfen is rapidly metabolized, principally by hydroxylation, and eliminated mainly in the faeces, and to a lesser extent in the urine.

Environmental properties

Vectra Felis should not enter water courses as this may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or with used containers.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dimethyl sulfoxide

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Spot-on applicator made of a multilayered complex of aluminium and polyethylene (PE) with a head made of HDPE, top-sealed with a liner complex (aluminium/polyester/sealable PE layer).

Pack sizes:
Cardboard box of 1, 3, 4, 6, 12 or 24 spot-on applicator(s).

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Vectra Felis should not enter water courses as this may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or with used containers.

7. MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
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Wooburn Green
High Wycombe
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HP10 0HH
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8. MARKETING AUTHORISATION NUMBER

Vm 15052/5025

9. DATE OF FIRST AUTHORISATION

6 June 2014

10. DATE OF REVISION OF THE TEXT

October 2022

Approved: 17 October 2022