ANNEX I

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

Each 0.9 ml spot-on applicator contains:

Active substances:
Dinotefuran 423 mg
Pyriproxyfen 42.3 mg

Excipients:

Qualitative composition of excipients and other constituents
Dimethyl sulfoxide

Colourless to pale yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each 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.

3.3 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.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The safety of the veterinary medicinal product has not been established in cats younger than 7 weeks or weighing less than 0.6 kg (see section 3.3).

After accidental ingestion of the veterinary medicinal 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 3.9), 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.

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

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 veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cats:

Rare (1 to 10 animals / 10,000 animals treated):	Scale (slight)[1,2], Erythema[1,2], Alopecia[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site reaction (e.g. erythema, pruritus, lesion, inflammation, residue (white dry)[1,3], hair change (wet haircoat)[1,3]) Hyperactivity

	Tachypnoea Muscle tremor[1,4] Lethargy[1,4]

[1] Transient.
[2] Usually disappear spontaneously without treatment.
[3] May persist up to 7 days, however, are usually not noticeable after 48 hours. These changes do not affect the safety or the efficacy of the veterinary medicinal product.
[4] In particular after application site licking.

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 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

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

Pregnancy and lactation:

Use only according 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.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Spot-on use.

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.

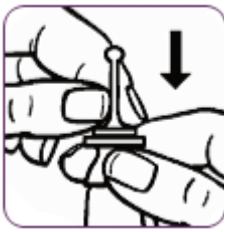
Care should be taken to apply the veterinary medicinal product only onto intact (undamaged) cat's skin.

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.

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

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.

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:

QP53AX73.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

Following topical application, the two active substances 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 veterinary medicinal 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

The veterinary medicinal product is dangerous for fish and other aquatic organisms.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 Special precautions for storage

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

5.4 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) in cardboard box.

Pack sizes:
Cardboard box of 1, 3, 4, 6, 12 or 24 spot-on applicator(s) (0.9 ml each).
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 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.
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

Ceva Santé Animale

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/165/001–004
EU/2/14/165/006–007

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 06/06/2014

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

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

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 1, 3, 4, 6, 12 and 24 spot-on applicators

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectra Felis 423 mg/42.3 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.9 ml spot-on applicator contains:
Dinotefuran 423 mg
Pyriproxyfen 42.3 mg

3. PACKAGE SIZE

1 spot-on applicator
3 spot-on applicators
4 spot-on applicators
6 spot-on applicators
12 spot-on applicators
24 spot-on applicators

4. TARGET SPECIES

Cats.

5. INDICATION(S)

Treatment and prevention of infestations with fleas for 1 month.
Prevention of flea multiplication for 3 months.

6. ROUTES OF ADMINISTRATION

Spot-on use. For external application to the skin.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use immediately.

9. SPECIAL STORAGE PRECAUTIONS

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

Ceva Santé Animale

14. MARKETING AUTHORISATION NUMBERS

EU/2/14/165/001 (1 spot-on applicator)
EU/2/14/165/002 (3 spot-on applicators)
EU/2/14/165/006 (4 spot-on applicators)
EU/2/14/165/003 (6 spot-on applicators)
EU/2/14/165/004 (12 spot-on applicators)
EU/2/14/165/007 (24 spot-on applicators)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Spot-on applicator

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectra Felis

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Dinotefuran 423 mg and pyriproxyfen 42.3 mg.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use immediately.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each 0.9 ml spot-on applicator contains:

Active substances:
Dinotefuran 423 mg
Pyriproxyfen 42.3 mg

Colourless to pale yellow spot-on solution.

3. Target species

Cats.

4. Indications for use

This veterinary medicinal product kills fleas (*Ctenocephalides felis*) on infested cats and prevents further infestations for one month. It also prevents the multiplication of fleas, by inhibiting immature flea emergence in the cat's environment, for 3 months.

5. 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.

6. Special warnings

Special warnings:
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.

Special precautions for safe use in the target species:
For external use only.
Apply only to the skin surface. Do not administer orally or via any other route.
The safety of this veterinary medicinal product has not been established in cats younger than 7 weeks of age or weighing less than 0.6 kg (see section "Contraindications").
After accidental ingestion of the veterinary medicinal 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 (as described in section "Advice on correct administration"), 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.
In case of suspicion of dermatitis (itch and skin irritation), seek for veterinary advice.

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 veterinary medicinal 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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation in adult female cats. Use only according to the benefit-risk assessment by the responsible veterinarian.
Laboratory studies with the active substances, dinotefuran or pyriproxyfen, in rats and rabbits have not produced any evidence of birth defects or other harmful effects in the developing embryo or foetus (teratogenic, foetotoxic) or harmful effects for the mother (maternotoxic effects).
In rats, dinotefuran has been shown to cross the blood-milk barrier and is excreted in the milk.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:
No 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.

Major incompatibilities:
None known.

7. Adverse events

Cats:

Rare (1 to 10 animals / 10,000 animals treated):
Scale (slight)[1,2], Erythema[1,2], Alopecia[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Application site reaction (e.g. erythema, pruritus, lesion, inflammation, residue (white dry)[1,3], hair change (wet haircoat)[1,3]); Hyperactivity; Tachypnoea; Muscle tremor[1,4]; Lethargy[1,4]

[1] Transient.

[2] Usually disappear spontaneously without treatment.
[3] May persist up to 7 days, however, are usually not noticeable after 48 hours. These changes do not affect the safety or the efficacy of the veterinary medicinal product.
[4] In particular after application site licking.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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 using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

Spot-on use.

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

Dosage:
Use one spot-on applicator for one administration on one cat only.
The use in cats younger than 7 weeks or weighing less than 0.6 kg is not recommended.
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 and 4.23 to 70.5 mg pyriproxyfen/kg bodyweight for cats which weigh between 0.6 kg and 10 kg.

Treatment schedule:
Following a single administration, the veterinary medicinal product will prevent flea infestation for one month and 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.

9. Advice on correct administration

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.


10. Withdrawal periods

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 which is stated on the carton and spot-on applicator after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: use immediately.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
This veterinary medicinal product 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.
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 or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/14/165/001–004
EU/2/14/165/006–007

Cardboard box containing 1, 3, 4, 6, 12 or 24 spot-on applicator(s) of 0.9 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

06/2025

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Ceva Santé Animale
8 rue de Logrono
33500 Libourne
France
Tel: +800 35 22 11 51
E-mail: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:
Ceva Santé Animale
10, av. de La Ballastière
33500 Libourne
France

AB7 SANTE
Chemin des Monges
31450 Deyme
France

17. Other information

Mechanisms of action:
The two active substances in the veterinary medicinal product spread over the body surface of the cat within the first day after application. The active substances act directly on the cat's coat without any need to infiltrate the blood flow. The parasite comes in contact with the treated cat and is then killed.
Dinotefuran kills insects by targeting their nervous system.
Pyriproxyfen targets the immature stages of insects (eggs, larvae, pupae) by disruption of their reproduction and development. Flea eggs, larvae and pupae are present in the environment.
The veterinary medicinal product kills fleas within 2 hours after application of the product or 2 hours after infestation of the treated animal.