

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard boxes of 1, 3, 4, 6, 12, 24 and 48 spot-on applicators

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectra 3D spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each spot-on applicator contains dinotefuran 196 mg / pyriproxyfen 17.4 mg / permethrin 1429 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
48 spot-on applicators

4. TARGET SPECIES

Dogs > 10-25 kg

5. INDICATIONS

Treatment and prevention of infestations with ticks and fleas up to 1 month.
Prevention of flea multiplication for 2 months.

Repels (prevents biting) flying insects such as sand flies, mosquitoes and stable flies for 1 month.

Kills mosquitoes and stable flies for 1 month.

6. ROUTES OF ADMINISTRATION

Spot-on use for external application to the skin.



Do not use on cats.

Avoid contact of the product with your skin, eyes or mouth.

Children should avoid contact with the dog during 4 hours after treatment.

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”

Do not use on cats.

Avoid contact of the product with your skin, eyes or mouth.

Children should avoid contact with the dog during 4 hours after treatment.

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



14. MARKETING AUTHORISATION NUMBERS

Vm 15052/5022

15. BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Spot-on applicator label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectra 3D > 10-25 kg



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

dinotefuran 196 mg / pyriproxyfen 17.4 mg / permethrin 1429 mg

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Vectra 3D spot-on solution for dogs 1.5–4 kg
Vectra 3D spot-on solution for dogs > 4–10 kg
Vectra 3D spot-on solution for dogs > 10–25 kg
Vectra 3D spot-on solution for dogs > 25–40 kg
Vectra 3D spot-on solution for dogs > 40 kg

2. Composition

1 ml contains:

Active substances:

Dinotefuran	54 mg
Pyriproxyfen	4.84 mg
Permethrin	397 mg

Each spot-on applicator delivers:

Weight of dog (kg)	Colour of applicator cap	Volume (ml)	Dinotefuran (mg)	Pyriproxyfen (mg)	Permethrin (mg)	N-methyl pyrrolidone
1.5-4 kg	Yellow	0.8	44	3.9	317	q.s. 0.8 ml
> 4-10 kg	Teal	1.6	87	7.7	635	q.s. 1.6 ml
> 10-25 kg	Blue	3.6	196	17.4	1,429	q.s. 3.6 ml
> 25-40 kg	Purple	4.7	256	22.7	1,865	q.s. 4.7 ml
> 40 kg	Red	8.0	436	38.7	3,175	q.s. 8.0 ml

The veterinary medicine is a pale-yellow spot-on solution, packaged in single dose spot-on applicators.

3. Target species

Dogs

4. Indications for use

Fleas:

This veterinary medicine kills fleas on infested animals and prevents further infestations for one month. It is effective against the following fleas found on dogs (*Ctenocephalides canis* and *Ctenocephalides felis*). This veterinary medicine also prevents the multiplication of fleas for two months after use by inhibiting flea egg hatching (ovicidal activity) and by inhibiting the transformation of immature fleas into adult fleas.

Ticks:

This veterinary medicine kills and repels ticks (*Rhipicephalus sanguineus* and *Ixodes ricinus* ticks are controlled for one month; *Dermacentor reticulatus* ticks are controlled for up to three weeks).

If ticks are present when this veterinary medicine is applied, the ticks may not all be killed within the first 48 hours after use, but they may be killed within a week. To remove ticks, it is recommended to use an appropriate tick removal device.

Sand flies, mosquitoes and stable flies:

The veterinary medicine repels (prevents biting) flying insects such as sand flies (*Phlebotomus perniciosus*), mosquitoes (*Culex pipiens*, *Aedes aegypti*) and stable flies (*Stomoxys calcitrans*) for one month after use. It also kills mosquitoes (*Aedes aegypti*) and stable flies for one month after use.

5. Contraindications



Do not use on cats (see 'Special warnings'). Due to their unique physiology and inability to metabolise permethrin (one of the active substances in this veterinary medicine), this veterinary medicine must not be used on cats. If applied to a cat, or ingested by a cat that actively grooms a recently treated dog, this veterinary medicine may have serious harmful effects.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

Special warnings:

All dogs within the household should be treated. Cats in the household should only be treated with a veterinary medicinal product authorised for use in cats.

Fleas can infest the dog'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 veterinary medicinal product remains effective when treated animals are immersed in water (e.g. swimming, bathing). Water immersion repeated weekly for one month and starting 48 hours after treatment, as well as shampooing 2 weeks after treatment do not affect the efficacy of this product.

However, in case of frequent shampooing, or bathing within 48 hours after treatment, the duration of activity may be reduced.

Special precautions for safe use in the target species:

For external use only.

In case of suspicion of dermatitis (itch and skin irritation), seek for veterinary advice. Do not use on cats. If the veterinary medicine is accidentally swallowed it can cause convulsions in cats that could be fatal.

In case of accidental exposure, wash the cat with shampoo or soap, and seek veterinary advice immediately. To prevent cats from being accidentally exposed to the veterinary medicine, keep cats away from treated dogs until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog which has been treated with this veterinary medicine. In case of exposure of this type seek veterinary advice immediately.

The safety of this veterinary medicine has not been established in dogs younger than 7 weeks or weighing less than 1.5 kg.

Care should be taken to avoid contact between the veterinary medicine and the eyes of the dog. If in eyes, immediately flush with water.

The attachment of a single tick after treatment cannot be excluded. For this reason the transmission of infectious diseases cannot be completely excluded if conditions are favourable.

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

Do not eat, drink or smoke while handling the veterinary medicinal product.

People with known hypersensitivity to any of the ingredients should avoid contact with the veterinary medicinal product.

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant.

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.

This 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.
- 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 thoroughly flushed with water.
- Children must not handle treated dogs for at least four hours after administration of the veterinary medicinal product. It is therefore recommended to treat dogs in the evening, or before taking them for a walk.
- On the day of treatment, treated dogs should not be permitted to sleep with their owners, especially children.
- Used applicators should be disposed of immediately and not left within the sight or reach of children.

If skin or eye irritation persists, or if the veterinary medicinal product is accidentally swallowed, seek medical advice immediately and show the package leaflet or the label to the physician.

Other precautions

Wait for the application site to dry before allowing the treated dog to come in contact with fabrics or furnishings.

Special precautions for the protection of the environment

Treated dogs should not be allowed to enter surface water for 48 hours after treatment to avoid adverse effects on aquatic organisms. See also section “ Special precautions for disposal”.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established in dogs during pregnancy and lactation or in animals intended for breeding.

Use only according to the benefit-risk assessment by the responsible veterinarian. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects.

Studies, with each active ingredient (dinotefuran, pyriproxyfen or permethrin), in rats and rabbits have not produced any evidence of toxicity on pregnant or lactating animals. Dinotefuran has been shown to pass into the milk of lactating animals.

Overdose:

Apart from erythema and cosmetic hair coat changes at the site of application, no adverse reactions were observed in healthy puppies aged 7 weeks, topically treated 7 times at 2-week intervals and with up to 5 times the highest recommended dose. After accidental ingestion of the highest recommended dose, vomiting, salivation and diarrhoea may occur, however these should resolve without treatment.

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):
Application site reaction ¹ (e.g. Erythema, Pruritus), Discomfort ^{1,2} , Behavioural disorder (e.g. Hyperactivity, Vocalisation, Anxiety), Neurological disorder (e.g. Muscle tremor), Systemic disorder (e.g. Lethargy, Anorexia)
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Application site reaction ³ (e.g. Hair change (wet appearance, spiking), Residue), Digestive tract disorder (e.g. Vomiting, Diarrhoea), Ataxia (e.g. Unsteady movement), Convulsion

¹ Mild and transient. If signs persist or worsen, veterinary advice should be sought.

² At the application site.

³ Transient, these signs are usually not noticeable after 48 hours.

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 using the contact details at the end of this leaflet, or via your national reporting system at:

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. 1 applicator per dog.

Care should be taken to apply the veterinary medicine only onto intact (undamaged) dog's skin.

Dosage:

Determine the correct size of spot-on applicator needed for your dog (the use in dogs younger than 7 weeks or weighing less than 1.5 kg is not recommended, see also section "Special warnings").

The minimum recommended dose is 6.4 mg dinotefuran/kg body weight, 0.6 mg pyriproxyfen/kg body weight and 46.6 mg permethrin/kg body weight, equivalent to 0.12 ml of the veterinary medicine per kg body weight.

The following table shows the size of spot-on applicator to be used according to the weight of the dog:

Weight of dog (kg)	Colour of applicator cap	Volume (ml)	Applicator to be used	
1.5-4 kg	Yellow	0.8	1 applicator of	Vectra 3D for dogs 1.5-4 kg
> 4-10 kg	Teal	1.6		Vectra 3D for dogs > 4-10 kg
> 10-25 kg	Blue	3.6		Vectra 3D for dogs > 10-25 kg
> 25-40 kg	Purple	4.7		Vectra 3D for dogs > 25-40 kg
> 40 kg	Red	8.0		Vectra 3D for dogs > 40 kg

9. Advice on correct administration

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 dog should be standing or in a comfortable position for easy application. Part the hair until the skin is visible. Apply the veterinary medicine (as directed in step 4 below) slowly with the tip of the applicator on the skin.



Step 4

Use according to **4a** or **4b** recommendation:

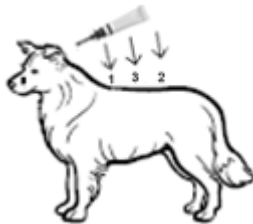
4a recommendation: Gently squeeze the applicator and apply the veterinary medicine to the skin along the dog's back, beginning between the shoulder blades, in the number of spots and order shown in the diagrams below and squeezing until the applicator is empty. Avoid superficial application to the dog's hair. The number of application spots will depend on the body weight of the dog.



Dogs from 1.5 to 4 kg body weight
1 yellow pipette per dog



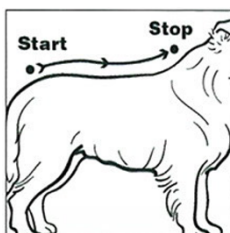
Dogs over 4 kg and up to 10 kg body weight
1 teal pipette per dog to be split in 2 spots



Dogs over 10 kg and up to 40 kg body weight
1 blue or purple pipette per dog to be split in
3 spots



Dogs over 40 kg body weight
1 red pipette per dog to be split in 4 spots



4b recommendation: Regardless of the dog's body weight, using the applicator tip, part the hair at the base of the tail and begin applying the veterinary medicine directly onto the skin in a continuous line from the base of the tail along the centre of the back all the way up to the shoulder blades, as shown in the diagram, squeezing the applicator until it is empty.

Treatment schedule:

Following a single administration, the veterinary medicine will prevent infestation for one month.

The treatment can be repeated once a month.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicine 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.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

This veterinary medicinal product should not enter water courses as it is 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 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 15052/5020

Vm 15052/5021

Vm 15052/5022

Vm 15052/5023

Vm 15052/5024

Cardboard box of 1, 3, 4, 6, 12, 24 or 48 spot-on applicators of 0.8 ml, 1.6 ml, 3.6 ml, 4.7 ml or 8.0 ml.

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:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom
Tel: 00800 35 22 11 51
Email for the reporting of adverse events: 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 three active ingredients in the veterinary medicine spread over the body surface of the dog within the first day after application and remain for 1 month. The actives act directly on the pets' coat without any need to infiltrate the blood flow. The parasite come in contact with the treated dog to be repelled and/or 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.

Permethrin repels and kills parasites by targeting their nervous system, leading to hyperexcitability (hot-foot effect for ticks), and resulting to knock-down, anti-attachment and anti-feeding actions against parasites.

Dinotefuran and permethrin work together, in synergy, for a faster onset of activity *in vivo*.

Flea insecticide activity starts within 12 hours after application.

POM-V

Veterinary Medicinal product subject to prescription
For animal treatment only

Gavin Hall
Approved: 15 January 2025