

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing 1, 3, 6, 12, 24, 60 or 120 pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Strectis 68mg/34mg spot-on solution for cats 0.5-5 kg
Fipronil / (S)-methoprene

2. STATEMENT OF ACTIVE SUBSTANCES

Each pipette delivers 68 mg of fipronil and 34 mg of (S)-methoprene

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

1 pipette
3 pipettes
6 pipettes
12 pipettes
24 pipettes
60 pipettes
120 pipettes

5. TARGET SPECIES

Cats

6. INDICATION(S)

*****Only for those countries where the product is available without a prescription*****

Treats and prevents flea infestations for 8 weeks.

Controls immature stages of fleas (eggs, larvae and pupae) for 6 weeks in the environment.

Treats and prevents tick infestations for 5 weeks.

*****Only for those countries where the product is available subject to prescription*****

Treats and prevents tick and flea infestations. Controls all flea stages (adults, eggs, larvae and pupae).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For external use only.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet for user warnings before using the product.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC 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.

*****Only for those countries where the product is available subject to prescription*****

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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4077

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Pipette label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Strectis 68mg/34mg spot-on solution for cats 0.5-5 kg
Spot-on



0.5-5 kg

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

68mg/34mg

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

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Strectis 68mg/34mg spot-on solution for cats 0.5-5 kg

Spot-on



0.5-5 kg

Fipronil 68 mg / (S)-methoprene 34 mg

2. NAME OF THE MARKETING AUTHORISATION HOLDER



3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Strectis 68mg/34mg spot-on solution for cats 0.5-5 kg

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

Marketing authorisation holder:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturers responsible for batch release:

Ceva Santé Animale
10, av. de La Ballastière
33500 Libourne
France

Klocke Verpackungs-Service GmbH
Max-Becker-Str. 6
76356 Weingarten
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Strectis 68mg/34mg spot-on solution for cats 0.5-5 kg
Fipronil 68 mg, (S)-methoprene 34 mg

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

This veterinary medicinal product is a clear spot-on yellow solution.

One pipette delivers:

	Volume of unit dose (ml)	Active substances		Excipients	
		Fipronil (mg)	(S)-methoprene (mg)	Butylhydroxyanisole E320 (mg)	Butylhydroxytoluene E321 (mg)
Cats 0.5-5 kg	0.4	68	34	0.08	0.08

4. INDICATIONS

Treatment and prevention of flea and/or tick infestations.

The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

Treatment and prevention of flea infestations (*Ctenocephalides spp*). Immediate insecticidal efficacy against new infestations with adult fleas persists for 8 weeks. Prevention of the multiplication of fleas by inhibiting the hatching of flea eggs (ovicidal activity) and the development of flea eggs into adult fleas for 6 weeks after application.

Treatment and prevention of tick infestation (*Rhipicephalus turanicus*). The product has immediate and persistent acaricidal efficacy for 5 weeks after application.

5. CONTRAINDICATIONS

Do not use on rabbits as adverse reactions and even death could occur.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Do not use on sick (e.g. systemic diseases, fever) or convalescent animals.

6. ADVERSE REACTIONS

Transient cosmetic effects such as spiking of the hair, wet appearance, dry residue or slight scaling may occur at the application site. These changes do not affect the safety or the efficacy of the product.

If animals lick the product, a transient hypersalivation mainly due to the excipients of the product may be noticed.

Alopecia and pruritus at application site have been reported very rarely based on post marketing safety experience.

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.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Dosage

One pipette per animal corresponding to the minimal recommended dose of 12 mg/kg body weight (bw) of fipronil and 6 mg/kg bw of (S)-methoprene.

Route

Spot-on use.

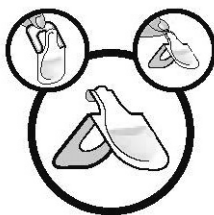
Administration

How to apply:

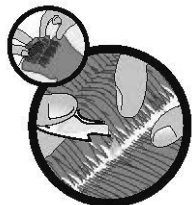
Disconnect one of the blisters from the card. This helps to avoid accidental opening of the adjacent blister in order to protect the still unopened pipettes from exposure to humidity. Open the blister with scissors. To avoid damaging the pipette, cut along the line marked with the scissors icon. Carefully peel back the foil from the cut off end and withdraw the pipette.



Hold the pipette upright. Tap lightly to ensure the entire liquid content is within the main body of the pipette. Bend the upper border strip backwards. Then the pipette can be set aside, if necessary. To open the pipette, snap off the top of the pipette along the scored line.



Part the coat between 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 content completely and directly onto the skin in one spot.



Application of the solution near the base of the neck minimises the possibility that the animal will lick the solution off. Care should be taken after the application that animals do not mutually lick off the solution.

Care should be taken to avoid excessive wetting of the hair with the product since this will cause a sticky appearance of hairs at the treatment spot.

Treatment can be repeated every 5 weeks or as considered appropriate for the type and level of parasitic exposure. In the absence of appropriate studies, the treatment should not be repeated at intervals of less than 2 weeks.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

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 after the expiry date which is stated on the pipette and on the carton after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:

All stages of fleas can infest the animal's basket, bedding, and regular resting areas such as carpets and soft furnishings. In cases of massive flea infestation and at the beginning of the control measures these areas should be treated with a suitable environmental product. To reduce environmental flea challenge, all animals living in the same household should also be treated with a suitable flea control product.

For the treatment and control of flea allergy dermatitis it is recommended that allergic patients and all other animals in the household should be treated on a regular basis.

No data in the effect of bathing/shampooing on the efficacy of the product in cats is available.

Special precautions for use in animals:

The attachment of single ticks after treatment cannot be ruled out. Therefore the transmission of infectious disease cannot be completely excluded if conditions are unfavourable.

For external use only. Do not administer orally.

Avoid contact with the eyes of the animals. If the product is in contact with eyes, rinse immediately with plenty of water.

Do not apply the product on wounds or skin lesions.

Wait for the application site to dry before allowing the treated animal to come into contact with valuable fabrics or furnishings.

It is important to make sure that the product is applied directly onto an area of dry skin where the animal cannot lick it off and to make sure that animals do not lick each other following treatment.

In the absence of additional safety studies, do not repeat the treatment at intervals of less than 2 weeks.

The safety of the product has not been established in cats younger than 8 weeks of age or weighing less than 0.5 kg of body weight (bw). Use only according to the benefit/risk assessment by the responsible veterinarian.

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

This veterinary medicinal product is considered to be irritating to the eyes mucous membrane and skin.

Avoid contact of the product with skin, eyes or mouth. People with known hypersensitivity to any of the ingredients should not treat their animal with the product.

Treated animals should not be handled or played with for at least 12-hours after treatment. Animals should be treated in the evening in order to minimise contact with the treated animal. On the day of treatment, treated animals should not be permitted to sleep with their owner, especially children.

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

Wash hands thoroughly after use.

In case of accidental spillage on skin, wash off immediately with soap and water. If the product accidentally gets into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists, or if the product is accidentally swallowed, seek medical advice immediately and show the package leaflet to the physician.

Keep stored pipettes in the original packaging until ready to use. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately in a proper way.

Pregnancy and lactation:

Studies carried out with fipronil in laboratory animals have not shown teratogenic or fetotoxic effects, although one study has shown developmental effects (e.g. neurotoxicity) in rats. The safety of the veterinary medicinal product has not been established in queens during pregnancy and lactation. Use only according to the risk-benefit assessment by the responsible veterinarian.

Overdose (symptoms, emergency procedures, antidotes):

No adverse effects were observed during a target animal safety study conducted in 8 weeks old kittens (average weight 0.5 kg on the first day of treatment) and treated on 7 consecutive occasions at 2 weeks intervals with up to 5x the recommended dose.

Interaction with other medicinal products and other forms of interaction:

None known.

Incompatibilities:

None known.

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

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

The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

Pharmacodynamic properties

Fipronil is an insecticide and acaricide belonging to the phenylpyrazole family. It acts by interacting with ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA), thereby blocking pre- and post-synaptic transfer of chloride ions across cell membranes. This results in uncontrolled activity of the central nervous system and death of arthropods such as fleas and ticks. Fipronil acts by contact. After topical administration, fipronil accumulates itself in sebaceous glands and is released progressively on hair surface via follicular ducts. Fipronil usually kills fleas within 24 hours and ticks within 48 hours.

(S)-methoprene is an insect growth regulator (IGR) of the class of compounds known as juvenile hormone analogues that inhibit the development of immature stages of insects. This compound mimics the action of juvenile hormone and causes impaired development and death of the developing stages of fleas. (S)-methoprene acts by contact. The on-animal ovicidal activity of (S)-methoprene results from either inhibition of egg laying by absorption through the cuticle of the adult fleas or from inhibition of egg hatching by direct penetration in newly laid eggs. In the environment of the treated animal, (S)-methoprene is also effective in the elimination of flea larvae and pupae, preventing these stages from developing into adults. This prevents further contamination with newly emerged adult fleas.

Pharmacokinetic particulars

Fipronil

Fipronil is poorly absorbed through the skin. After topical application in clinical conditions (licking not prevented), peak fipronil plasma concentrations (mean C_{max} 316 ng/ml) are rapidly attained (mean t_{max} approximately 8 h). Fipronil is slightly metabolized to fipronil sulfone.

Fipronil and its major metabolite are well-distributed in the haircoat after topical administration.

(S)-methoprene

Plasma concentrations of S-methoprene were generally below the limit of quantification (10 ng/mL) after topical application.

Pack sizes:

Cardboard box of 1, 3, 6, 12, 24, 60 and 120 pipettes.

Not all pack sizes may be marketed.

Pipettes are packed in child resistant blisters.

Approved 05 October 2022

