SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 0.4 ml pipette contains:

Active substances:

Fipronil	68 mg
(S)-methoprene	34 mg

Excipients:

Butylhydroxyanisole E320	0.08 mg
Butylhydroxytoluene E321	0.08 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.
Clear yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats

4.2 Indications for use, specifying the target species

Treatment and prevention of flea and/or tick infestations.

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 persists 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.

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

4.3 Contraindications

Do not use in rabbits, as adverse reactions and even death could occur.
Do not use in cases 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.

4.4 Special warnings for each target species

All stages of fleas can infest the cat's basket, bedding, and regular resting areas such as carpets and soft furnishings. In cases of massive flea infestation 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 on the effect of bathing/shampooing on the efficacy of the product in cats is available.

4.5 Special precautions for use

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 animal. 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 cat to come into contact with valuable fabrics or furnishings. It is important to make sure that the veterinary medicinal 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 product can cause mucous membrane, skin and eye irritation.
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 this 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 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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

Spot-on use

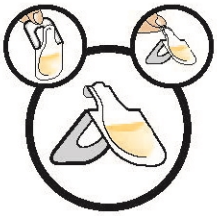
One pipette per animal corresponding to the minimal recommended dose of 12 mg/kg bw of fipronil and 6 mg/kg bw of (S)-methoprene.

How to apply:

Disconnect one of the blisters from the card. This helps to avoid accidental opening of the adjacent blisters in order to protect the still unopened pipettes from exposure to humidity. Open the blisters with scissors. To avoid damaging the pipette cut along the

line marked with the scissors icon. Carefully peal 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.

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

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, fipronil combinations.
ATCvet code: QP53AX65
The product is an insecticidal and acaricidal solution for topical use, containing an association of an adulticidal active ingredient, fipronil, in combination with an ovicidal and larvicidal active ingredient, (S)-methoprene.

5.1 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.

5.2 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.

5.3 Environmental properties

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole (E320).
Butylhydroxytoluene (E321).
Ethanol (anhydrous).
Diethylene glycol monoethyl ether.

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

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

The pipettes are made of:

Front foil:	Polypropylene / polyethylene terephthalate
Lidding foil:	Polyester / aluminium / polyester / polyethylene terephthalate

Pipettes are packed in child resistant blisters.

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

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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.
The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 15052/4077

9. DATE OF FIRST AUTHORISATION

02 February 2016

10. DATE OF REVISION OF THE TEXT

October 2022

Approved 05 October 2022