PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stronghold Plus 30 mg/5 mg spot-on solution >2.5–5 kg

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

30 mg selamectin/5 mg sarolaner/pipette

3. PACKAGE SIZE

3 x 0.5 ml
6 x 0.5 ml

4. TARGET SPECIES

Cats

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Spot-on use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store below 30 °C.
Do not remove the pipette from the blister until ready to use.

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

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5069

15. BATCH NUMBER

Lot

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

Veterinary medicinal product subject to prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Pipette}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stronghold Plus

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

>2.5–5 kg
30 mg selamectin/5 mg sarolaner

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. ROUTE(S) OF ADMINISTRATION

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stronghold Plus spot-on

>2.5–5 kg

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

selamectin/sarolaner

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stronghold Plus 15 mg/2.5 mg spot-on solution for cats ≤2.5 kg
Stronghold Plus 30 mg/5 mg spot-on solution for cats >2.5–5 kg
Stronghold Plus 60 mg/10 mg spot-on solution for cats >5–10 kg

2. COMPOSITION

Each unit dose (pipette) delivers:

Active substances:

Stronghold Plus spot-on solution	unit dose (ml)	selamectin (mg)	sarolaner (mg)
Cats ≤2.5 kg	0.25	15	2.5
Cats >2.5–5 kg	0.5	30	5
Cats >5–10 kg	1	60	10

Excipients:
Butylhydroxytoluene 0.2 mg/ml.

Clear, colourless to yellow spot-on solution.

3. TARGET SPECIES

Cats.

4. INDICATIONS FOR USE

For cats with, or at risk from, mixed parasitic infestations by ticks and fleas, lice, mites, gastrointestinal nematodes or heartworm. The veterinary medicinal product is exclusively indicated when use against ticks and one or more of the other target parasites is indicated at the same time.

Ectoparasites:
- For the treatment and prevention of flea infestations (*Ctenocephalides* spp.). The veterinary medicinal product has immediate and persistent flea killing activity against new infestations for 5 weeks. The product kills adult fleas before they lay eggs for 5 weeks. Through its ovicidal and larvicidal action, the veterinary medicinal product may aid in the control of existing environmental flea infestations in areas to which the animal has access.

- The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

- For reduction of the risk of infection with *Dipylidium caninum* via transmission by *Ctenocephalides felis* for one month after treatment. The effect is indirect due to the product's activity against the vector.

- Treatment of tick infestations. The veterinary medicinal product has immediate and persistent acaricidal effect for 5 weeks against *Ixodes ricinus* and *Ixodes hexagonus*, and 4 weeks against *Dermacentor reticulatus* and *Rhipicephalus sanguineus*.

- Treatment of ear mites (*Otodectes cynotis*).

- Treatment of biting lice infestations *(Felicola subrostratus*).

- Treatment of notoedric mange (*Notoedres cati*).

Ticks must attach to the host and commence feeding in order to be exposed to sarolaner.

Nematodes:
- Treatment of adult roundworms (*Toxocara cati*) and adult intestinal hookworms (*Ancylostoma tubaeforme).*

- Prevention of heartworm disease caused by *Dirofilaria immitis* with monthly administration.

5. CONTRAINDICATIONS

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

Do not use in cats that are suffering from concomitant disease, or are debilitated and underweight (for size and age).

6. SPECIAL WARNINGS

Special warnings:
It is recommended, in accordance with good veterinary practice, that all animals 6 months of age or more, living in countries where a vector exists should be tested for existing adult heartworm infections before beginning preventive use with the veterinary medicinal product.

This veterinary medicinal product is not effective against adult *D. immitis*. The administration to animals with adult heartworm infection did not pose safety concerns.

Whilst not routinely indicated, the potential benefits of performing periodic testing for heartworm infection in individual cases should be considered by the responsible veterinarian.

Ticks need to start feeding on the host to become exposed to sarolaner; therefore, the transmission of infectious tick-borne diseases cannot be excluded.

The efficacy of the veterinary medicinal product has not been established in cats with severe clinical signs of *N. cati*. Use of the veterinary medicinal product in such cases should be based on the benefit-risk assessment of the responsible veterinarian.

Special precautions for safe use in the target species:
Use of this veterinary medicinal product is indicated in cats aged at least 8 weeks old and weighing at least 1.25 kg bodyweight.

This veterinary medicinal product is to be applied to the skin surface only. Do not administer orally or parenterally.

Do not apply when the animal's hair coat is wet.

For ear mite treatment, do not apply directly to the ear canal.

It is important to apply the dose as indicated to prevent the animal from licking and ingesting the product. If significant ingestion occurs, transient gastrointestinal effects such as hypersalivation, emesis, soft faeces or reduced food consumption may be observed and should normally resolve without treatment.

Keep treated animals away from fires and other sources of ignition for at least 30 minutes or until the hair coat is dry.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product is harmful after ingestion. Keep the veterinary medicinal product in the original packaging until use, in order to prevent children from getting direct access to the veterinary medicinal product. Used pipettes should be disposed of immediately. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

The veterinary medicinal product may cause eye irritation. Avoid eye contact including hand-to-eye-contact. Avoid direct contact with treated animals until the application area is dry. Wash hands after use and wash off any veterinary medicinal product in contact with the skin immediately with soap and water. In case of accidental eye exposure, flush the eyes immediately with water, seek medical advice immediately and show the package leaflet or the label to the physician. People with sensitive skin or known allergy to veterinary medicinal products of this type should handle the veterinary medicinal product with caution.

Children are not allowed to play with treated cats for 4 hours after treatment. It is recommended to treat animals in the evening. On the day of treatment, treated animals should not be permitted to sleep in the same bed as their owner, especially children.

The veterinary medicinal product is highly flammable. Keep away from heat, sparks, open flame or other sources of ignition.

Pregnancy, lactation and fertility:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation or in animals intended for breeding. However, selamectin is considered safe for use in breeding, pregnant and lactating cats. While the safety of sarolaner has not been evaluated in breeding, pregnant or lactating cats, laboratory studies with sarolaner in rats and rabbits have not produced any evidence of teratogenic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interactions:
During clinical field testing, no interactions between this veterinary medicinal product and routinely used veterinary medicinal products were observed.

Overdose:
No clinically significant adverse reactions were observed in kittens from 8 weeks of age treated with up to 5 times the maximum recommended dose of the veterinary medicinal product for up to 8 consecutive treatments at 28 day intervals, apart from a single cat administered 5 times the maximum dose that displayed transient hypersensitivity to touch, piloerection, mydriasis and mild tremor which resolved without treatment.

After accidental ingestion of a full product dose, transient gastrointestinal effects such as salivation, soft faeces, emesis, and reduced food consumption may occur, however, these should resolve without treatment.

Major incompatibilities:
None known.

7. ADVERSE EVENTS

Cats:

Uncommon (1 to 10 animals / 1,000 animals treated):	Application site pruritus (itching)[1], application site alopecia (hair loss)[2] Erythema (redness)[2] Drooling[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Convulsions[3], ataxia (incoordination[3] Vomiting[3], diarrhoea[3]

[1] mild and transient.
[2] mild to moderate.
[3] mostly transient.

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 or the local representative of the marketing authorisation holder

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

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

Spot-on use.
The veterinary medicinal product should be administered as a single spot-on (topical) application in accordance with the following table (corresponding to a minimum of 6 mg/kg selamectin and 1 mg/kg sarolaner).

Bodyweight of cat (kg)	**Pipette content (ml)**	**Strength and number of pipettes to be administered**		
		15 mg/2.5 mg (yellow cap)	**30 mg/5 mg (orange cap)**	**60 mg/10 mg (green cap)**
≤2.5	0.25	1		
>2.5–5	0.5		1	
>5–10	1			1
>10	Appropriate combination of pipettes			

Fleas and ticks
For optimal control of tick and flea infestations, the veterinary medicinal product should be administered at monthly intervals and continued throughout the flea and/or tick season based on local epidemiological situations.

Following administration of the veterinary medicinal product, the adult fleas on the animal are killed within 24 hours, no viable eggs are produced, and larvae (found only in the environment) are also killed. This stops flea reproduction, breaks the flea lifecycle and may aid in the control of existing environmental flea infestations in areas to which the animal has access.

Prevention of heartworm disease
The veterinary medicinal product may be administered year-round or at least within one month of the animal's first exposure to mosquitoes and monthly thereafter until the end of the mosquito season. The final dose must be given within one month after the last exposure to mosquitoes. If a dose is missed and a monthly interval between dosing is exceeded, then immediate administration of the veterinary medicinal product and resumption of monthly dosing will minimise the opportunity for the development of adult heartworms. When replacing another heartworm preventive veterinary medicinal product in a heartworm disease prevention programme, the first dose of the veterinary medicinal product must be given within a month of the last dose of the former veterinary medicinal product.

Treatment of roundworm and hookworm infections
A single dose of the veterinary medicinal product should be administered. The need for and frequency of re-treatment should be in accordance with the advice of the prescribing veterinarian.

Treatment of biting lice
A single dose of the veterinary medicinal product should be administered.

Treatment of ear mites
A single dose of the veterinary medicinal product should be administered. Seek further veterinary examination 30 days after treatment to determine whether a second administration is necessary.

Treatment of notoedric mange
A single dose of the veterinary medicinal product should be administered.

9. ADVICE ON CORRECT ADMINISTRATION

This veterinary medicinal product is to be applied to the skin surface only. Do not administer orally or parenterally.

Do not apply when the animal's hair coat is wet.

For ear mite treatment, do not apply directly to the ear canal.

It is important to apply the dose as indicated to prevent the animal from licking and ingesting the product. If significant ingestion occurs, transient gastrointestinal effects such as hypersalivation, emesis, soft faeces or reduced food consumption may be observed and should normally resolve without treatment.

Apply topically to the skin at the base of the neck in front of the shoulder blades. The pipette should be removed from the protective package immediately prior to administration.

Holding the pipette upright, firmly depress the cap to puncture the applicator seal, then remove the cap.

Part the hair at the base of the cat's neck in front of the shoulder blades to expose a small area of skin. Apply the tip of the pipette directly to the skin without massaging.

Squeeze the pipette firmly 3–4 times to empty the contents in one spot. Avoid contact between the product and your fingers.

Transient cosmetic effects may occur at the application site such as temporary clumping or spiking of the hair, greasiness or dry white deposits, which normally resolve within 24 hours after product application. These effects do not affect the safety or efficacy of the veterinary medicinal product.

10. WITHDRAWAL PERIODS

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 30 °C.
Do not remove the pipette from the blister until ready to use.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton, blister and pipette 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.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.
The veterinary medicinal product should not enter water courses as this may be dangerous for fish and other aquatic organisms.
Containers and residual contents should be disposed of along with collected domestic refuse to avoid contamination of any water courses.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5068
Vm 42058/5069
Vm 42058/5070

The veterinary medicinal product is available in packs of three pipettes (all pipette sizes) and six pipettes (all pipette sizes).
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:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

17. OTHER INFORMATION

Selamectin is a semi-synthetic compound of the avermectin class. Selamectin has adulticidal, ovicidal and larvicidal activity against fleas. Therefore, it effectively breaks the flea life cycle by killing adults (on the animal), preventing the hatching of eggs (on the animal and in its environment) and by killing larvae (environment only). Debris from selamectin-treated pets kills flea eggs and larvae not previously exposed to selamectin and thus may aid in the control of existing environmental flea infestations in areas to which the animal has access. Selamectin is active against adult fleas (*Ctenocephalides* spp.) as well as mites (*Otodectes cynotis*, *Notoedres cati*), lice (*Felicola subrostratus*) and gastrointestinal nematodes (*Toxocara cati*, *Ancylostoma tubaeforme*). Activity has also been demonstrated against heartworm (*D. immitis)* larvae.

For fleas, the onset of efficacy is within 24 hours for 5 weeks after product application.

Sarolaner is an acaricide and insecticide belonging to the isoxazoline family. Sarolaner is active against adult fleas (*Ctenocephalides* spp.) as well as several tick species such as *Dermacentor reticulatus, Ixodes hexagonus, Ixodes ricinus*, and *Rhipicephalus sanguineus*.

For ticks (*I. ricinus*), the onset of efficacy is within 24 hours of attachment for one month after product application.

Gavin Hall
Approved: 16 December 2025