#### Veterinary medicine package leaflet

This medicine is dispensed with a veterinarian's prescription only For use in animals only

## 1. Name, form and strength of the veterinary medicine

Stronghold Plus Veterinary Spot-on solution for cat skin

## 2. Active ingredients

Each millilitre contains

selamectin	60.00mg
sarolaner	10.00mg
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For a list of the inactive ingredients and allergens in this medicine see section 13.

## 3. What is this medicine intended for?

This product is intended for cats with, or at risk from, mixed parasitic infestations by ticks, fleas, lice, mites, gastrointestinal nematodes or heartworm (dirofilariasis). This veterinary medicinal product is exclusively indicated in cases of infestation with ticks together with one or more of the other target parasites 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 aids in the control of environmental flea infestations in the area in which
  the animal is located.
- The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).
- Treatment of tick infestations. The veterinary medicinal product has immediate and persistent mite killing activity for 5 weeks against *Ixodes ricinus* and *Ixodes* hexagonus, and for 4 weeks against *Dermacentor reticulatus* and *Rhipicephalus* sanguineus.
- Treatment of ear mites (Otodectes cynotis).
- Treatment of biting lice infestations (*Felicola subrostratus*). Ticks must attach to the host's body and commence feeding on it, in order to be exposed to sarolaner.

#### Nematodes (roundworms):

- Treatment of adult roundworms (Toxocara cati) and adult intestinal hookworms (Ancylostoma tubaeforme).
- Prevention of a disease caused by heartworm (*Dirofilaria immitis*) with monthly administration.

A medicine of the anti-parasitic group.

## 4. Contraindications

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

Do not use if the cat is sensitive to the active ingredients or to any of the excipients in the product.

# 5. Side effects

Use of this veterinary medicinal product may cause mild and transient pruritus at the application site. Mild to moderate alopecia at the application site, erythema and drooling have been uncommonly observed.

Neurological symptoms (convulsions, ataxia) and gastrointestinal symptoms (emesis, diarrhoea) have been reported very rarely based on post-marketing safety data. In most cases these symptoms are transient.

You can report side effects to the Ministry of Health by following the link Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <u>https://sideeffects.health.gov.il</u>

# 6. Target animals

Cats

## 7. Dosage and method of administration

#### Solution for topical use.

Stronghold Plus Veterinary should be administered as a single 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)	Tube content (ml)	Strength and number of tubes to be administered		
		Stronghold Plus Veterinary 15 mg/2.5 mg (yellow cap)	Stronghold Plus Veterinary 30 mg/5 mg (orange cap)	Stronghold Plus Veterinary 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 tubes			

Application schedule: Fleas and ticks:

For optimal control of tick or flea infestations, the veterinary medicinal product should be administered once a month and continued throughout the pest season. Following administration of the product, the adult fleas are killed within 24 hours, no new eggs are produced, and larvae (found only in the environment) are also killed. This stops flea reproduction, breaks the flea lifecycle and can aid in the control of existing environmental flea infestations in areas to which the cat has access.

### Prevention of heartworm disease (dirofilariasis):

The product may be administered year-round or at least within one month of the cat'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 the interval between dosing is greater than one month, then immediate administration of the product and resumption of monthly dosing will minimise the risk of adult heartworms developing. When replacing another heartworm preventive product in a heartworm disease prevention programme, the first dose of the product must be given within a month of the last dose of the former veterinary medicinal product.

Treatment of roundworm and hookworm infestations:

A single dose of the product should be administered. The need for and frequency of re-administration should be in accordance with the advice of the prescribing veterinarian.

### Treatment of biting lice:

A single dose of the product should be administered.

#### Treatment of ear mites:

A single dose of the product should be administered. Schedule a veterinary examination about 30 days after treatment to determine whether a second administration is necessary.

## 8. How to use this medicine

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

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

For ear mite treatment, do not apply the product in the ear canal.

It is important to apply the product as described below to prevent the cat from licking and ingesting the product. If significant ingestion occurs, transient gastrointestinal effects such as hypersalivation, vomiting, soft faces or reduced food consumption may occur. These effects should normally resolve without treatment. Apply topically to the skin at the base of the neck in front of the shoulder blades. Only remove the tube from the protective package immediately prior to administration. Holding the tube upright, firmly depress the cap to puncture the tube, 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 tube to the skin without massaging.

Squeeze the tube firmly 3-4 times to empty the contents. Avoid contact between the product and your fingers.

Transient cosmetic effects may occur at the site of administration, such as stiff hair, greasiness or white powder. These effects normally resolve within 24 hours after administration and do not affect product safety or efficacy.

# 9. Withdrawal period

Not applicable.

# 10. Warnings

Special warnings about treating the target animal with this medicine

It is recommended that all animals 6 months of age or more, living in countries where a vector exists should be tested for heartworm infection before beginning preventive use with this veterinary medicinal product.

This veterinary medicinal product is not effective against adult *D. immitis*. The administration to cats with adult heartworm infection did not pose safety concerns. Although not obligatory, the benefits of performing periodic testing for heartworm infection should be considered by the veterinarian.

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

• Special warnings about the safety of using this medicine in animals

This veterinary medicinal product is intended for use in cats aged at least 8 weeks old and weighing at least 1.25 kg.

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

## Special safety precautions for the person administering the medicine

The product may be harmful after ingestion. Keep the product in the original packaging until use in order to prevent children from getting direct access to the product. Used tubes should be disposed of immediately. In case of accidental ingestion, seek medical help immediately and show the package or package leaflet to the doctor. The product may cause eye irritation. Avoid eye contact including hand-to-eyecontact.

Avoid direct contact with the treated animal until the application area is dry. Wash hands after use, and wash off any product that has come in contact with the skin with soap and water.

If accidental eye exposure occurs, flush the eyes immediately with water and seek medical attention.

People with sensitive skin or known allergy to veterinary medicinal products of this type, should handle the veterinary medicinal product with caution.

Do not allow children to play with the treated cat 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. • Additional warnings

This product is highly flammable; keep it away from heat, sparks, open flame or other sources of ionition.

Gestating and lactating animals

The safety of this 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 a benefit-risk assessment made by the prescribing veterinarian.

Drug interactions and other interactions

During field testing, no interactions between Stronghold Plus Veterinary and other widely used veterinary medicinal products were observed.

Overdose

No significant adverse reactions were observed in kittens from 8 weeks of age treated with up to 5 times the maximum recommended dose of the product for 8 consecutive treatments at 28 day intervals, apart from a single cat administered 5 times the maximum dose that displayed transient sensitivity 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, vomiting, and reduced food consumption may occur, however these effects resolve without treatment.

Incompatibility
 None known

# 11. Storage instructions

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- <u>Storage conditions</u> Store the product below 30°C. Do not peel off the foil until ready to use.

# 12. Instructions for the disposal of unused product

Selamectin may adversely affect aquatic organisms. To prevent contamination of water, do not dispose of the tubes and unused product via household waste. Dispose of any unused veterinary medicinal product or waste material obtained from using a veterinary medicinal product in the same manner as toxic waste; do not discard down a drain.

# 13. Additional information

 In addition to the active ingredients, this medicine also contains: Isopropyl Alcohol (IPA) Dipropyleneglycol Monomethylether (DPGMME)

Butylated Hydroxytoluene (BHT)

- What the medicine looks like and contents of the pack: Each polypropylene tube contains 0.25, 0.5, or 1 ml clear, colourless to yellow solution.
- Pack sizes:
- Cap colours signify the following packages:

Tubes with yellow cap contain 0.25 ml composed of 15 mg selamectin and 2.5 mg sarolaner.

Tubes with orange cap contain 0.5 ml composed of 30 mg selamectin and 5 mg sarolaner.

Tubes with green cap contain 1 ml composed of 60 mg selamectin and 10 mg sarolaner.

Each pack contains 3 or 6 tubes. Not all pack sizes may be marketed.

- Registration holder: Zoetis Israel Holding B.V., 5 Atir Yeda st., Kfar Saba
- Manufacturer: Zoetis LLC (Subsidiary of Zoetis Inc.), 2605 East Kilgore Road, Kalamazoo, Michigan USA

# Revised in February 2022 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health National Drug Registry: 166-50-35507-00

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