PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard Carton / 3 and 6 pipettes}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stronghold 240 mg spot-on solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

240 mg selamectin/pipette

3. PACKAGE SIZE

3 x 2.0 ml
6 x 2.0 ml

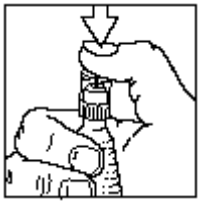
4. TARGET SPECIES

Dogs 20.1–40.0 kg.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Spot-on use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C. Store in the original package in a dry place.

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5062

15. BATCH NUMBER

Lot {number}

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
To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Foil label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stronghold 240 mg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

240 mg selamectin for dogs 20.1 – 40.0 kg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

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

6. ROUTE(S) OF ADMINISTRATION

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stronghold 15 mg spot-on solution for cats and dogs ≤ 2.5 kg
Stronghold 30 mg spot-on solution for dogs 2.6–5.0 kg
Stronghold 45 mg spot-on solution for cats 2.6–7.5 kg
Stronghold 60 mg spot-on solution for cats 7.6–10.0 kg
Stronghold 60 mg spot-on solution for dogs 5.1–10.0 kg
Stronghold 120 mg spot-on solution for dogs 10.1–20.0 kg
Stronghold 240 mg spot-on solution for dogs 20.1–40.0 kg
Stronghold 360 mg spot-on solution for dogs 40.1–60.0 kg

2. COMPOSITION

Each single-dose (pipette) delivers:

	unit dose (ml)	selamectin (mg)
Stronghold 15 mg for cats and dogs	0.25	15
Stronghold 30 mg for dogs	0.25	30
Stronghold 45 mg for cats	0.75	45
Stronghold 60 mg for cats	1	60
Stronghold 60 mg for dogs	0.5	60
Stronghold 120 mg for dogs	1	120
Stronghold 240 mg for dogs	2	240
Stronghold 360 mg for dogs	3	360

Excipients:

Butylated hydroxytoluene 0.8 mg/ml.

Colourless to yellow solution.

3. TARGET SPECIES

Dogs and cats.

4. INDICATIONS FOR USE

Cats and dogs:

- **Treatment and prevention of flea infestations** caused by *Ctenocephalides* spp. for one month following a single administration. This is as a result of the adulticidal, larvicidal and ovicidal properties of the veterinary medicinal product. The veterinary medicinal product is ovicidal for 3 weeks after administration. Through a reduction in the flea population, monthly treatment of pregnant and lactating animals will also aid in the prevention of flea infestations in the litter up to seven weeks of age. The veterinary medicinal product can be used as part of a treatment strategy for flea allergy dermatitis and through its ovicidal and larvicidal action may aid in the control of existing environmental flea infestations in areas to which the animal has access.

- **Prevention of heartworm disease** caused by *Dirofilaria immitis* with monthly administration. The veterinary medicinal product may be safely administered to animals infected with adult heartworms, however, 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 with the administration of the veterinary medicinal product. It is also recommended that dogs should be tested periodically for adult heartworm infections, as an integral part of a heartworm prevention strategy, even when the veterinary medicinal product has been administered monthly. This veterinary medicinal product is not effective against adult *D. immitis*.

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

Cats:
- Treatment of biting lice infestations (*Felicola subrostratus*)
- Treatment of adult roundworms (*Toxocara cati*)
- Treatment of adult intestinal hookworms (*Ancylostoma tubaeforme*).

Dogs:
- Treatment of biting lice infestations (*Trichodectes canis*)
- Treatment of sarcoptic mange (caused by *Sarcoptes scabiei*)
- Treatment of adult intestinal roundworms (*Toxocara canis*).

5. CONTRAINDICATIONS

Do not use in animals under 6 weeks of age. Do not use in cats that are suffering from concomitant disease, or are debilitated and underweight (for size and age).

6. SPECIAL WARNING(S)

Special warnings:
Animals may be bathed 2 hours after treatment without loss of efficacy.
Do not apply when the animal's hair coat is wet. However, shampooing or soaking the animal 2 or more hours after treatment will not reduce the efficacy of the product.
For ear mite treatment, do not apply directly to the ear canal.
It is important to apply the dose as indicated to minimise the quantity that the animal can lick off. If significant licking does occur, a brief period of hypersalivation may rarely be observed in cats.

Special precautions for safe use in the target species:
This veterinary medicinal product is to be applied to the skin surface only. Do not administer orally or parenterally.
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:
This product is highly flammable; keep away from heat, sparks, open flames or other sources of ignition.
Do not smoke, eat or drink while handling the product.

Wash hands after use and wash off any 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.
Avoid direct contact with treated animals until the application site is dry. On the day of treatment, children must not handle treated animals and the animals 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.
People with sensitive skin or known allergy to veterinary medicinal products of this type should handle the veterinary medicinal product with caution.

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

Other precautions:
Do not allow treated animals to bathe in water courses until at least two hours after treatment administration.

Pregnancy and lactation:
Can be used in pregnant and lactating cats and dogs.

Fertility:
Can be used in breeding cats and dogs.

Interaction with other medicinal products and other forms of interaction:
In extensive field testing no interactions between the veterinary medicinal product and routinely used veterinary medicinal products or medical or surgical procedures were observed.

Overdose:
The veterinary medicinal product was administered at 10 times the recommended dose, and no undesirable effects were observed. The veterinary medicinal product was administered at 3 times the recommended dose to cats and dogs infected with adult heartworms and no undesirable effects were observed. The veterinary medicinal product was also administered at 3 times the recommended dose to breeding male and female cats and dogs, including pregnant and lactating females nursing their litters and at 5 times the recommended dose to ivermectin-sensitive Collies, and no undesirable effects were observed.

7. ADVERSE EVENTS

Cats:

Rare (1 to 10 animals / 10,000 animals treated):
application site alopecia[1,2], application site hair changes[3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
application site irritation[1,4], neurological signs (including seizures)[5]

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):
application site hair changes[3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
neurological signs (including seizures)[5]

[1]Normally self-resolving, but symptomatic therapy may be applicable in some circumstances.
[2]Mild and transient.
[3]Local temporary clumping of the hair at the application site and/or an occasional appearance of a small quantity of a white powder which typically disappear within 24 hours of treatment administration and does not affect either the safety or efficacy of the veterinary medicinal product.
[4]Transient and focal.
[5]Reversible as with other macrocyclic lactones.

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, ROUTE(S) AND METHOD OF ADMINISTRATION

Spot-on use.

Apply to the skin at the base of the neck in front of the shoulder blades.
The veterinary medicinal product should be administered topically as a single application of a single-dose delivering a minimum of 6 mg/kg selamectin. When concurrent infestations or infections in the same animal are to be treated with the veterinary medicinal product, only one application of the recommended 6 mg/kg dose should be administered at any one time. The appropriate length of the treatment period for individual parasites is specified below.

Administer the veterinary medicinal product in accordance with the following table:

Cats (kg)	**Pipette cap colour**	**mg of selamectin dispensed**	**Potency (mg/ml)**	**Administered volume (nominal pipette size, ml)**
≤ 2.5	Rose	15	60	0.25
2.6–7.5	Blue	45	60	0.75
7.6–10.0	Taupe	60	60	1.0
> 10		Appropriate combination of pipettes	60	Appropriate combination of pipettes

Dogs (kg)	Pipette cap colour	mg of selamectin dispensed	Potency (mg/ml)	Administered volume (nominal pipette size, ml)
≤ 2.5	Rose	15	60	0.25
2.6–5.0	Violet	30	120	0.25
5.1–10.0	Brown	60	120	0.5
10.1–20.0	Red	120	120	1.0
20.1–40.0	Green	240	120	2.0
40.1–60.0	Plum	360	120	3.0
> 60		Appropriate combination of pipettes	60/120	Appropriate combination of pipettes

Flea treatment and prevention (cats and dogs)

Animals older than six weeks of age:

Following administration of the veterinary medicinal product to the animal, adult fleas and larvae are killed and no viable eggs are produced. This stops flea reproduction and may aid in the control of existing environmental flea infestations in areas to which the animal has access.

For the prevention of flea infestations, the veterinary medicinal product should be administered to the animal at monthly intervals throughout the flea season, starting one month before fleas become active. This ensures that fleas infesting the animal are killed, no viable flea eggs are produced by these fleas, and larvae (found only in the environment) are also killed. This breaks the flea life cycle and prevents flea infestations.

For use as part of a treatment strategy for flea allergy dermatitis the veterinary medicinal product should be administered at monthly intervals.

Treatment of pregnant and lactating animals to prevent flea infestations in puppies and kittens:

Through a reduction in the flea population, monthly treatment of pregnant and lactating animals will aid prevention of flea infestation in the litter up to seven weeks of age.

Prevention of heartworm disease (cats and dogs)

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 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 medication.

Treatment of roundworm infections (cats and dogs)

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

Treatment of biting lice (cats and dogs)

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

Treatment of ear mites (cats)

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

Treatment of ear mites (dogs)

A single dose of the veterinary medicinal product should be administered. Loose debris should be gently removed from the external ear canal at each treatment. A further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

Treatment of hookworm infections (cats)

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

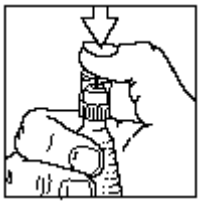
Treatment of sarcoptic mange (dogs)

For complete elimination of the mites, a single dose of the veterinary medicinal product should be administered for two consecutive months.

9. ADVICE ON CORRECT ADMINISTRATION

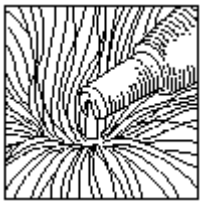
Remove the pipette from its protective package.

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



Part the hair at the base of your animal'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 to empty the contents in one spot. Avoid contact between the veterinary medicinal product and your fingers.



Do not apply when the hair coat is wet. However, shampooing or soaking the animal 2 or more hours after treatment will not reduce the efficacy of the veterinary medicinal product.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 30 °C. Store in the original package in a dry place.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label 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.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
The veterinary medicinal product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5060
Vm 42058/5061
Vm 42058/5062
Vm 42058/5063
Vm 42058/5064
Vm 42058/5065
Vm 42058/5066
Vm 42058/5067

The veterinary medicinal product is available in packs of three pipettes (for all pipette sizes), six pipettes (for all pipette sizes except 15 mg selamectin), or fifteen pipettes (for 15 mg selamectin pipette size only).
Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

May 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database.

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

Local representatives and contact details to report suspected adverse reactions:

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Zoetis Belgium SA
Mercuriusstraat 20
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17. OTHER INFORMATION

Approved 06 March 2024