SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELAPRO 360 mg spot-on solution for very large dogs (40.1–60.0 kg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3.0ml pipette contains:

Active substance:
Selamectin 360 mg

Excipients:
Butylhydroxytoluene 2.4 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.
A clear, colourless to yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

- **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 product. The 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 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. Selamectin 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 beginning medication with Selamectin.

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 Selamectin has been administered monthly. This product is not effective against adult *D. immitis.*

- **Treatment of ear mites** (*Otodectes cynotis*).
- Treatment of biting lice infestations (*Trichodectes canis*)
- Treatment of sarcoptic mange (caused by *Sarcoptes scabiei*)
- Treatment of adult intestinal roundworms (*Toxocara canis*).

4.3 Contraindications

Do not use in animals under 6 weeks of age.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

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

Other precautions

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

4.6 Adverse reactions (frequency and seriousness)

On rare occasions application of the veterinary medicinal product may produce a local temporary clumping of the hair at the application site and/or an occasional appearance of a small quantity of a white powder. This is normal and will disappear typically within 24 hours of treatment administration and does not affect either the safety or efficacy of the veterinary medicinal product.

Very rarely, as with other macrocyclic lactones, reversible neurological signs, including seizures, have been observed after use of the veterinary medicinal product in dogs.

The frequency of adverse reactions is defined using the following convention:
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

These products can be used in breeding, pregnant and lactating dogs.

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.
Animals should be weighed accurately prior to treatment.

These products should be administered 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 in accordance with the following table:

Dogs (kg)	Product	mg of selamectin dispensed	Administered volume (nominal pipette size, ml)
≤ 2.5	SELAPRO 15 mg spot-on solution for dogs and cats (< 2.5 kg)	15	0.25
2.6–5.0	SELAPRO 30 mg spot-on solution for very small dogs (2.6–5.0 kg)	30	0.25
5.1–10.0	SELAPRO 60 mg spot-on solution for small dogs (5.1–10.0 kg)	60	0.5
10.1–20.0	SELAPRO 120 mg spot-on solution for medium dogs (10.1–20.0 kg)	120	1.0
20.1–40.0	SELAPRO 240 mg spot-on solution for large dogs (20.1–40.0 kg)	240	2.0
40.1–60.0	SELAPRO 360 mg spot-on solution for very large dogs (40.1–60.0 kg)	360	3.0
> 60	Appropriate combination of pipettes		

Flea treatment and prevention
Following administration of the veterinary medicinal product, the adult fleas on the animal are killed, 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.

For the prevention of flea infestations, the veterinary medicinal product should be administered at monthly intervals throughout the flea season, starting one month before fleas become active. Through a reduction in the flea population, monthly treatment of pregnant and lactating animals will aid prevention of flea infestations in the litter up to seven weeks of age.

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

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 medication.

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

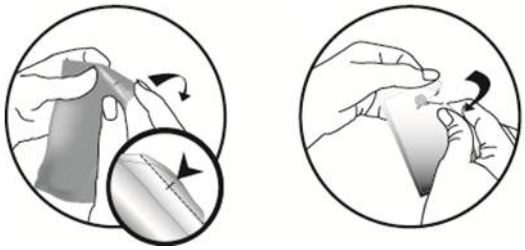
Treatment of biting lice
A single dose of the veterinary medicinal product should be administered.

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

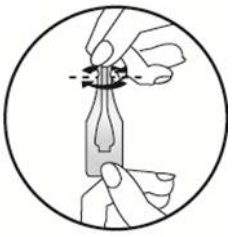
Treatment of sarcoptic mange
For complete elimination of the mites, a single dose of the veterinary medicinal product should be administered for two consecutive months.

Route and method of administration:
External use only, spot-on use.
Only remove pipette from sachet immediately prior to use.

Remove the pipette from the outer sachet using scissors or fold along diagonal line to expose nick; tear back at nick.



Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Twist or snap back the tip.



Part the coat on the back of the animal at the base of the neck in front of 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 contents completely and directly onto the skin in one spot without massaging.

Avoid contact between the product and your fingers.

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

No undesirable effects were observed in target animal safety studies when animals received 10 times the recommended dose.
No undesirable effects were observed in dogs infected with adult heartworms which received 3 times the recommended dose.
No undesirable effects were observed in breeding male and female dogs, including pregnant and lactating females nursing their litters which received 3 times the recommended dose and no undesirable effects were observed in ivermectin-sensitive Collies receiving 5 times the recommended dose.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiparasitic products, insecticides and repellents, macrocyclic lactones.
ATC vet code: QP54AA05.

5.1 Pharmacodynamic properties

Selamectin is a semi-synthetic compound of the avermectin class. Selamectin paralyses and/or kills a wide range of invertebrate parasites through interference with their chloride channel conductance causing disruption of normal neurotransmission. This inhibits the electrical activity of nerve cells in nematodes and muscle cells in arthropods leading to their paralysis and/or death.

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.

Activity has also been demonstrated against heartworm larvae.

5.2 Pharmacokinetic particulars

Following spot on administration selamectin is absorbed from the skin reaching maximum plasma concentrations approximately 3 days after administration in dogs. Following absorption from the skin selamectin distributes systemically and is slowly eliminated from plasma as manifested in detectable plasma concentrations in dogs 30 days after administration of a single topical dose at 6 mg/kg. The prolonged persistence and slow elimination of selamectin from plasma is reflected in the terminal elimination half-life value of 11 days in dogs. The systemic persistence of selamectin in plasma and the lack of extensive metabolism provide effective concentrations of selamectin for the duration of the inter-dosing interval (30 days).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene (E321)
Dipropylene glycol mono methyl ether
Isopropyl alcohol

6.2 Major Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Do not store above 30^{o}C. Store in the original package in order to protect from light and moisture.

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is supplied in single dose pipettes which are moulded from a film composed of 3 layers: a polypropylene/COC/polypropylene, solvent free lacquer laminate and a copolymer of polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachet composed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.

The products are supplied in boxes of 1, 3, 4, 6 and 24 unit dose 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 product should be disposed of in accordance with local requirements.

These products 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.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

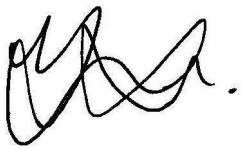
Vm 02000/4434

9. DATE OF FIRST AUTHORISATION

23 October 2018

10. DATE OF REVISION OF THE TEXT

June 2023



Approved: 14 June 2023