ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton of 1, 3, 4, 6 or 24 pipettes containing 1.0 ml pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELAPRO 120 mg spot-on solution for medium dogs (10.1–20.0 kg)
Selamectin

2. STATEMENT OF ACTIVE SUBSTANCES

One 1.0 ml pipette contains:

120 mg selamectin

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

1 x 1.0ml pipette
3 x 1.0ml pipettes
4 x 1.0ml pipettes
6 x 1.0ml pipette
24 x 1.0 ml pipettes

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

- For the treatment and prevention of flea infestation (*Ctenocephalides spp.*),
- the prevention of heartworm disease (*Dirofilaria immitis*),
- the treatment of ear mite (*Otodectes cynotis*),
- the treatment of biting lice infestations (*Trichodectes canis)*,
- the treatment of sarcoptic mange *(*caused by *Sarcoptes scabiei),*
- the treatment of adult intestinal roundworms *(Toxocara canis)*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

External use only. Spot-on use.
For dogs weighing 10.1–20.0 kg.
Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: mm/yyyy

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Store in the original package in order to protect from light and moisture.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4432

17. MANUFACTURER'S BATCH NUMBER

BN:

- Adult Fleas
- Flea larvae
- Flea eggs
- Ear mites
- Heartworm
- Roundworm
- Sarcoptic mange
- Biting lice

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachet for 1.0 ml pipette/blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELAPRO 120 mg spot-on solution for medium dogs (10.1–20.0 kg)
Selamectin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One 1.0 ml pipette contains:
120 mg selamectin

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

1.0 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on use.
Only remove pipette from sachet immediately prior to use.
<Pictogram of a spot-on pipette>

5. WITHDRAWAL PERIODS

Not applicable.

6. BATCH NUMBER

BN:

7. EXPIRY DATE

EXP: mm/yyyy

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
Dog <Pictogram of a dog>

9. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1.0 ml pipette/blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELAPRO 120 mg

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook

3. EXPIRY DATE

mm/yyyy

4. BATCH NUMBER

XXXX XXX

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

<Pictogram of a dog>

6. PHARMACEUTICAL FORM

<Pictogram of a spot-on pipette>

7. VOLUME

1.0 ml

8. TARGET ANIMAL WEIGHT RANGE

10.1-20.0 kg

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

SELAPRO 120 mg spot-on solution for medium dogs (10.1–20.0 kg)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
(UK)
Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
Northern Ireland

Manufacturer responsible for batch release:
(UK)
Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELAPRO 120 mg spot-on solution for medium dogs (10.1–20.0 kg)
Selamectin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each 0.25ml pipette contains:

Active substance:
Selamectin 120 mg
Excipients:
Butylhydroxytoluene 0.8 mg

A clear, colourless to yellow solution.

4. INDICATION(S)

- **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*).

5. 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.

6. ADVERSE REACTIONS

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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

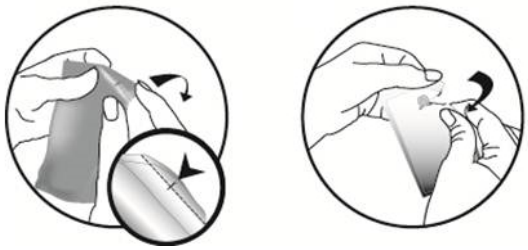
Treatment of biting lice
A single dose of the veterinary medicinal product should be administered.

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.

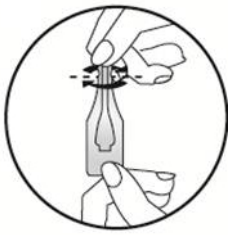
Treatment of sarcoptic mange
For complete elimination of the mites, a single dose of the veterinary medicinal product should be administered for two consecutive months.

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.

9. ADVICE ON CORRECT ADMINISTRATION

It is important to make sure that the product is applied to an area where the animal cannot lick it off and to make sure that animals do not lick each other following treatment.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 30ºC. Store in the original package in order to protect from light and moisture.
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the sachet and carton after {EXP}.

12. SPECIAL WARNING(S)

For Animal Treatment Only.

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.

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

Overdose (symptoms, emergency procedures, antidotes):
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.

Interaction with other medicinal products and other forms of interaction:
In extensive field testing no interactions for other similar selamectin containing spot-on products and routinely used veterinary medicinal products or medical or surgical procedures were observed.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

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.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

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