# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARTON 30 mg, 60 mg, 120 mg, 240 mg, 360 mg (3 and 6 pipettes)**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Selaspot 30 mg spot-on solution for dogs 2.6–5.0 kg
Selaspot 60 mg spot-on solution for dogs 5.1–10.0 kg
Selaspot 120 mg spot-on solution for dogs 10.1–20.0 kg
Selaspot 240 mg spot-on solution for dogs 20.1–40.0 kg
Selaspot 360 mg spot-on solution for dogs 40.1–60.0 kg
selamectin

## 2. STATEMENT OF ACTIVE SUBSTANCES

selamectin 30 mg
selamectin 60 mg
selamectin 120 mg
selamectin 240 mg
selamectin 360 mg

## 3. PHARMACEUTICAL FORM

Spot-on solution.

## 4. PACKAGE SIZE

3 pipettes
6 pipettes

0.25 ml
0.5 ml
1.0 ml
2.0 ml
3.0 ml

## 5. TARGET SPECIES

Dogs weighing 2.6–5.0 kg.
Dogs weighing 5.1–10.0 kg.
Dogs weighing 10.1–20.0 kg.
Dogs weighing 20.1–40.0 kg.
Dogs weighing 40.1–60.0 kg.

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on use.
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD(S)

## 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

## 10. EXPIRY DATE

EXP {month/year}

## 11. SPECIAL STORAGE CONDITIONS

Store in the original blister package in order to protect from light.

## 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. To be supplied only on veterinary prescription.

## 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

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 50146/4047

## 17. MANUFACTURER'S BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**FOIL LABEL, 15 mg, 30 mg, 45 mg, 60 mg, 120 mg, 240 mg, 360 mg**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

selamectin

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

15 mg selamectin
30 mg selamectin
45 mg selamectin
60 mg selamectin
120 mg selamectin
240 mg selamectin
360 mg selamectin

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

## 4. ROUTE(S) OF ADMINISTRATION

Spot-on use

## 5. WITHDRAWAL PERIOD(S)

## 6. BATCH NUMBER

Lot {number}

## 7. EXPIRY DATE

EXP {month/year}

## 8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET:
# Selaspot 30 mg spot-on solution for dogs 2.6–5.0 kg
# Selaspot 60 mg spot-on solution for dogs 5.1–10.0 kg
# Selaspot 120 mg spot-on solution for dogs 10.1–20.0 kg
# Selaspot 240 mg spot-on solution for dogs 20.1–40.0 kg
# Selaspot 360 mg spot-on solution for dogs 40.1–60.0 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
Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

Manufacturer responsible for batch release:
Bimeda Animal Health Limited
Unit 2/3/4 Airton Close,
Tallaght, Dublin 24,
Ireland

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Selaspot 30 mg spot-on solution for dogs 2.6–5.0 kg
Selaspot 60 mg spot-on solution for dogs 5.1–10.0 kg
Selaspot 120 mg spot-on solution for dogs 10.1–20.0 kg
Selaspot 240 mg spot-on solution for dogs 20.1–40.0 kg
Selaspot 360 mg spot-on solution for dogs 40.1–60.0 kg

selamectin

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

Each pipette contains:

**Active substance:**

| | | |
|---|---|---|
| Selaspot 30 mg for dogs | selamectin | 30 mg |
| Selaspot 60 mg for dogs | selamectin | 60 mg |
| Selaspot 120 mg for dogs | selamectin | 120 mg |
| Selaspot 240 mg for dogs | selamectin | 240 mg |
| Selaspot 360 mg for dogs | selamectin | 360 mg |

**Excipients:**

Butylhydroxytoluene (E321) 0.8 mg/ml.

Clear, colourless to slightly 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 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 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 beginning medication with The 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 product has been administered monthly. This veterinary medicinal 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:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, 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 weighing 2.6 kg–5.0 kg (Selaspot 30 mg spot-on solution for dogs 2.6–5.0 kg)
Dogs weighing 5.1 kg–10.0 kg (Selaspot 60 mg spot-on solution for dogs 5.1–10.0 kg)
Dogs weighing 10.1 kg–20.0 kg (Selaspot 120 mg spot-on solution for dogs 10.1–20.0 kg)
Dogs weighing 20.1 kg–40.0 kg (Selaspot 240 mg spot-on solution for dogs 20.1–40.0 kg)
Dogs weighing 40.1 kg–60.0 kg (Selaspot 360 mg spot-on solution for dogs 40.1–60.0 kg)

## 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 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 product in accordance with the following table:

| Dogs (kg) | Pipette cap colour | mg of selamectin dispensed | Potency (mg/ml) | Administered volume (nominal pipette size, ml) |
|---|---|---|---|---|
| 2.6-5.0 | Purple | 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 | Teal | 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**

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:

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

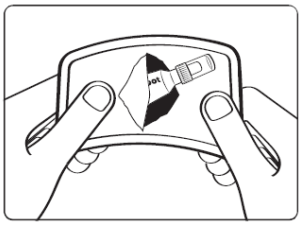
**Treatment of biting lice**
A single dose of the veterinary medicinal product should be administered.

**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 each treatment. A further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

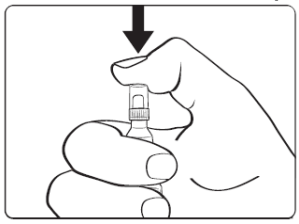
**Treatment of sarcoptic mange**
For complete elimination of the mites, a single dose of the veterinary medicinal product should be administered for two consecutive months.

## 9. ADVICE ON CORRECT ADMINISTRATION

Remove the pipette from its protective package

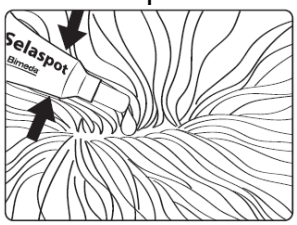


Holding the pipette upright, firmly depress the cap to puncture the applicator seal, then remove the cap.



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.

Store in the original blister package in order to protect from light. This veterinary medicinal product does not require any special temperature storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister card after EXP.

## 12. SPECIAL WARNING(S)

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.

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.
It is important to apply the dose as indicated to minimise the quantity that the animal can lick off.

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.
The product is a skin and eye irritant. 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 pipettes 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:
Selamectin is toxic for aquatic organisms. Treated dogs should not be allowed to enter surface water for 48 hours after treatment, to avoid adverse effects on aquatic organisms.

Pregnancy, lactation and fertility:
Can be used in pregnant, lactating and breeding dogs.

Interactions with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
No undesirable effects were observed after the administration of 10 times the recommended dose. Selamectin was administered at 3 times the recommended dose to dogs infected with adult heartworms and no undesirable effects were observed. Selamectin was also administered at 3 times the recommended dose to breeding male and female 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.

Incompatibilities:
Not applicable.

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

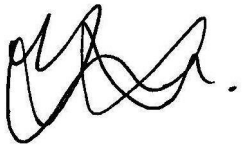
Medicines should not be disposed of via wastewater.
Selamectin may adversely affect fish or certain water-borne organisms on which they feed. Containers and residual contents should be disposed of along with collected domestic refuse to avoid contamination of any water courses.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2023

## 15. OTHER INFORMATION

Selaspot 30 mg, 60 mg, 120 mg, 240 mg and 360 mg for dogs is available in packs of three pipettes and six pipettes.
Not all pack sizes may be marketed.



Approved: 23 June 2023