ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Selehold 60 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.5 ml pipette contains:
Selamectin 60 mg

3. PACKAGE SIZE

1 x 0.5 ml
3 x 0.5 ml
6 x 0.5 ml
15 x 0.5 ml

4. TARGET SPECIES

Dogs

5.1–10.0 kg

5. INDICATIONS

 *Ctenocephalides* spp.

 *Dirofilaria immitis*

 *Otodectes cynotis*

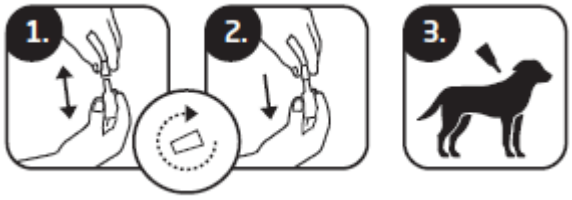
 *Trichodectes canis*

 *Sarcoptes scabiei*

 *Toxocara canis*

6. ROUTES OF ADMINISTRATION

Spot-on use.



7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package in order to protect from moisture and light.

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 OF THE MARKETING AUTHORISATION HOLDER

KRKA

14. MARKETING AUTHORISATION NUMBER

Vm 01656/3059

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BAG

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Selehold

5.1–10.0 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

selamectin

60 mg

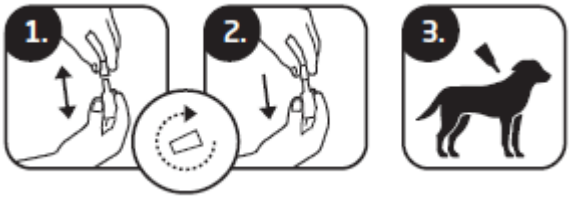
3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

KRKA



MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Selehold

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

5.1–10.0 kg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

KRKA

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each 0.25 ml pipette contains:

Active substance:
Selamectin 30 mg

Excipient:
Butylhydroxytoluene (E321) 0.2 mg

Each 0.5 ml pipette contains:

Active substance:
Selamectin 60 mg

Excipient:
Butylhydroxytoluene (E321) 0.4 mg

Each 1.0 ml pipette contains:

Active substance:
Selamectin 120 mg

Excipient:
Butylhydroxytoluene (E321) 0.8 mg

Each 2.0 ml pipette contains:

Active substance:
Selamectin 240 mg

Excipient:
Butylhydroxytoluene (E321) 1.6 mg

Each 3.0 ml pipette contains:

Active substance:
Selamectin 360 mg

Excipient:
Butylhydroxytoluene (E321) 2.4 mg

Clear, colourless to yellow to brown solution.

3. Target species

Dogs (2.6-5.0 kg)
Dogs (5.1-10.0 kg)
Dogs (10.1-20.0 kg)
Dogs (20.1-40.0 kg)
Dogs (40.1-60.0 kg)

4. Indications for use

- **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.

- **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*) 
- **Prevention of heartworm disease** 

caused by *Dirofilaria immitis* with monthly administration

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. Special warnings

Special warnings:
Do not apply when the animal's hair coat is wet. Avoid frequent swimming or shampooing the animal because the maintenance of effectiveness of the veterinary medicinal product in these cases has not been investigated.
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.
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 the veterinary medicinal product has been administered monthly. This veterinary medicinal product is not effective against adult *D. immitis.*
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

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:
Wash hands after use and wash off any veterinary medicinal 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.
This veterinary medicinal 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 veterinary medicinal product.
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:
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 and lactation:
Can be used during pregnancy and lactation.

Fertility:
Can be used in breeding animals.

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

Overdose:
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.

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Application site hair changes[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Neurological signs (including seizures)[2]

[1]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.
[2]Reversible as with other macrocyclic lactones.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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: {national system details}.

8. Dosage for each species, routes 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 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)	Pipette cap colour	Selamectin (mg)	Potency (mg/ml)	Volume (nominal tube size – ml)
2.6-5.0	Violet	30	120	0.25
5.1-10.0	Orange	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	Dark blue	360	120	3.0
>60	/	Appropriate combination of pipettes	/	Appropriate combination of pipettes
For dogs ≤2.5 kg, please consider the following pipette:				
≤2.5	Pink	15	60	0.25

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 need for treatment should be determined by the prescribing veterinarian and should be based on the local epidemiological situation (see section 6). For prevention of heartworm disease, the veterinary medicinal product should be administered within one month of the animal's first exposure to mosquitoes and monthly thereafter until 1 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. The need for extended treatment should be determined by the prescribing veterinarian. 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.

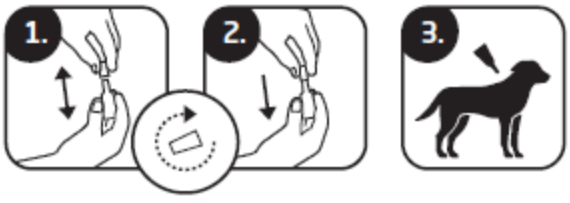
Treatment of ear mites
A single dose of the veterinary medicinal product should be administered. Loose debris should be gently removed from the external ear canal at the time of treatment. A further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

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.

9. Advice on correct administration

How to apply:

1. Remove the pipette from its packaging. Hold the pipette in an upright position, twist and pull the cap off.
2. Turn the cap around and place the other end of the cap back on the pipette. Push and twist the cap to break the seal, then remove the cap from the pipette.
3. Part the coat at the base of the neck in front of the shoulder blades until the skin is visible. Place the tip of the pipette onto the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin 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 periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original package in order to protect from moisture and 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 labels and carton 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 or household waste.

This veterinary medicinal product should not enter water courses as selamectin may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 01656/3058
Vm 01656/3059
Vm 01656/3060
Vm 01656/3061
Vm 01656/3062

Translucent polypropylene unit-dose pipette with polyethylene or polyoxymethylene or polypropylene closure with spike packaged into a laminated triplex bag composed of polyester, aluminium and polyethylene.
1 ml pipette containing 0.25 ml of solution.
1 ml pipette containing 0.5 ml of solution
3 ml pipette containing 1.0 ml of solution
6 ml pipette containing 2.0 ml of solution
6 ml pipette containing 3.0 ml of solution

Pack sizes:
Cardboard box containing 1, 3, 6 or 15 pipettes.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

August 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia
Tel:

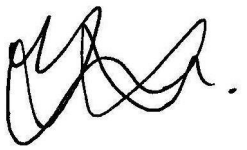
Manufacturer responsible for batch release:
KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

TAD Pharma GmbH
Heinz-Lohmann-Straße 5
27472 Cuxhaven
Germany

Local representatives and contact details to report suspected adverse reactions:

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

17. Other information



Approved: 13 February 2024