SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Selehold 240 mg spot-on solution for dogs 20.1–40.0 kg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml pipette contains:
Active substance:
Selamectin 240 mg

Excipients:
Butylhydroxytoluene (E321) 1.6 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.
Clear, colourless to yellow to brown solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs (20.1-40.0 kg)

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.
- **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

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

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 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 product has been administered monthly. This 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.

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

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.
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.
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

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.

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.

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).

4.7 Use during pregnancy, lactation or lay

Can be used in breeding, pregnant or lactating dogs.

4.8 Interaction with other 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.

4.9 Amounts to be administered and administration route

The 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)
20.1-40.0	Green	240	120	2.0

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 4.4). 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.

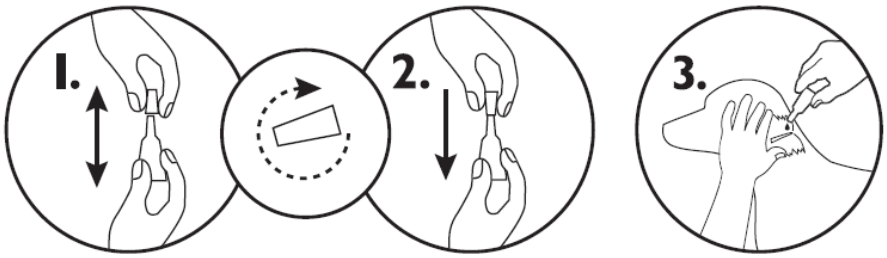
Method and route of administration: spot-on use.

Apply to the skin at the base of the neck in front of the shoulder blades.

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 product and your fingers.



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

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL 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 4 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 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 values of 9 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

Isopropyl alcohol
Butylhydroxytoluene (E321)
Dimethyl sulfoxide

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

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.

6.5 Nature and composition of immediate packaging

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.
Cardboard box containing 1, 3, 6 or 15 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.

Selamectin 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

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

8. MARKETING AUTHORISATION NUMBER

Vm 01656/4140

9. DATE OF FIRST AUTHORISATION

15 November 2018

10. DATE OF REVISION OF THE TEXT

August 2021

Approved: 27/08/21