

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Selames 15 mg spot-on solution for cats and dogs  $\leq 2.5$  kg

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.25 ml pipette contains:

### Active substance:

Selamectin 15 mg

### Excipients:

| Qualitative composition of excipients and other constituents | Quantitative composition if that information is essential for proper administration of the veterinary medicinal product |
|--|---|
| Isopropyl alcohol  |   |
| Butylhydroxytoluene (E321)                                   | 0.2 mg  |
| Dimethyl sulfoxide   |   |

Clear, colourless to yellow to brown solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cats and dogs ( $\leq 2.5$  kg).

### 3.2 Indications for use for each target species

#### Cats and dogs:

- **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.
- **Treatment of ear mites** (*Otodectes cynotis*)

#### Cats:

- **Treatment of biting lice infestations** (*Felicola subrostratus*)
- **Treatment of adult roundworms** (*Toxocara cati*)
- **Treatment of adult intestinal hookworms** (*Ancylostoma tubaeforme*)

#### Dogs:

- **Treatment of biting lice infestations** (*Trichodectes canis*)

- **Treatment of sarcoptic mange** (caused by *Sarcoptes scabiei*)
- **Treatment of adult intestinal roundworms** (*Toxocara canis*)

### 3.3 Contraindications

Do not use in animals under 6 weeks of age.

Do not use in cats that are suffering from concomitant disease or are debilitated and underweight (for size and age).

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

### 3.4 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 animals 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.

### 3.5 Special precautions for use

#### 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.

### 3.6 Adverse events

Cats:

|  |  |
|--|--|
| Rare<br>(1 to 10 animals / 10,000 animals treated):                            | Application site alopecia <sup>1,2</sup><br>Application site hair changes <sup>3</sup><br>Hypersalivation <sup>6</sup> |
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Application site irritation <sup>2,4</sup><br>Neurological signs (including seizures) <sup>5</sup>                     |

Dogs:

|  |  |
|--|--|
| Rare<br>(1 to 10 animals / 10,000 animals treated):                            | Application site hair changes <sup>3</sup>           |
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Neurological signs (including seizures) <sup>5</sup> |

<sup>1</sup>Mild and transient.

<sup>2</sup>Normally self-resolving, but symptomatic therapy may be applicable in some circumstances.

<sup>3</sup>Local temporary clumping of the hair 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.

<sup>4</sup>Transient and focal.

<sup>5</sup>Reversible as with other macrocyclic lactones.

<sup>6</sup>If significant licking occurs, may be observed for a brief period.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Fertility:

Can be used in breeding animals.

### 3.8 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.

### 3.9 Administration routes and dosage

Spot-on use.

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:

| Cats and dogs (kg) | Pipette cap colour | Selamectin (mg) | Potency (mg/ml) | Volume (nominal tube size – ml) |
|--------------------|--------------------|-----------------|-----------------|---------------------------------|
| ≤2.5               | Pink               | 15              | 60              | 0.25                            |

#### **Flea treatment and prevention (cats and dogs)**

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 (cats and dogs)**

The need for treatment should be determined by the prescribing veterinarian and should be based on the local epidemiological situation (see section 3.4). 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 (cats and dogs)**

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

#### **Treatment of biting lice (cats and dogs)**

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

#### **Treatment of ear mites (cats)**

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

#### **Treatment of ear mites (dogs)**

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 hookworm infections (cats)**

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

#### **Treatment of sarcoptic mange (dogs)**

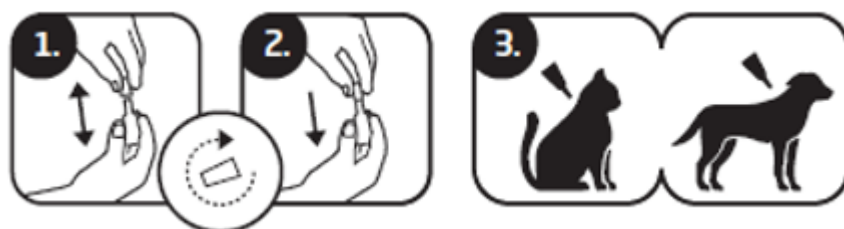
For complete elimination of the mites, a single dose of the veterinary medicinal product should be administered for two consecutive months.

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 veterinary medicinal product and your fingers.



### **3.10 Symptoms of overdose (and where applicable, emergency procedures and 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 cats and 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 cats and 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.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

Not applicable.

### **3.12 Withdrawal periods**

Not applicable.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code : QP54AA05.**

### **4.2 Pharmacodynamics**

Selamectin is a semi-synthetic compound of the avermectin class. Selamectin paralyzes 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.

### **4.3 Pharmacokinetics**

Following spot on administration selamectin is absorbed from the skin reaching maximum plasma concentrations approximately 5 and 4 days after administration in cats and dogs, respectively. Following absorption from the skin selamectin distributes systemically and is slowly eliminated from plasma as manifested in detectable plasma concentrations in dogs and cats 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 8 and 9 days in cats and dogs respectively. 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).

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

None known.

### **5.2 Shelf life**

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

### **5.3 Special precautions for storage**

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

### **5.4 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. 1 ml pipette containing 0.25 ml of solution.

#### Pack sizes:

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

Not all pack sizes may be marketed.

### **5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

Medicines should not be disposed of via wastewater or household waste.

The 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 national collection systems applicable to the veterinary medicinal product concerned.

**6. NAME OF THE MARKETING AUTHORISATION HOLDER**

KRKA, d.d., Novo mesto

**7. MARKETING AUTHORISATION NUMBER(S)**

**8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: {DD/MM/YYYY}

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month YYYY}>

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

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

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**



## **A. LABELLING**

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX}

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Selames 15 mg spot-on solution

### 2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.25 ml pipette contains:

selamectin                      15 mg

### 3. PACKAGE SIZE

1 x 0.25 ml  
3 x 0.25 ml  
6 x 0.25 ml  
15 x 0.25 ml

### 4. TARGET SPECIES

Cats and dogs

≤ 2.5 kg



### 5. INDICATIONS



*Ctenocephalides* spp.



*Dirofilaria immitis*



*Otodectes cynotis*



*Felicola subrostratus*, *Trichodectes canis*



*Toxocara cati*, *Toxocara canis*



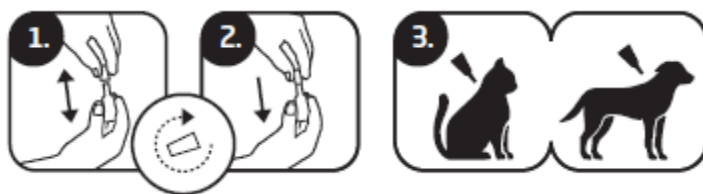
*Ancylostoma tubaeforme*



*Sarcoptes scabiei*

### 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 light and moisture.

**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, d.d., Novo mesto

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot {number}

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

**BAG**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Selames

≤ 2.5 kg



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

selamectin

15 mg

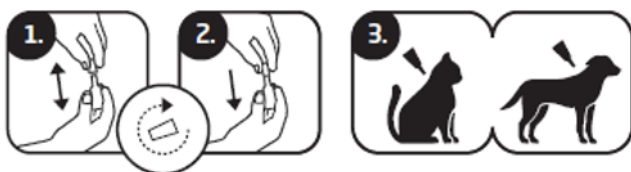
**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Marketing authorisation holder:  
KRKA



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

**PIPETTE**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Selames



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

$\leq 2.5$  kg

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Selames 15 mg spot-on solution for cats and dogs  $\leq 2.5$  kg

### 2. Composition

Each 0.25 ml pipette contains:

#### Active substance:

Selamectin 15 mg

#### Excipient:

Butylhydroxytoluene (E321) 0.2 mg

Clear, colourless to yellow to brown solution.

### 3. Target species

Cats and dogs ( $\leq 2.5$  kg).



### 4. Indications for use

Cats and dogs:

- **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.

- **Treatment of ear mites (*Otodectes cynotis*)**



Cats:

- **Treatment of biting lice infestations (*Felicola subrostratus*)**



- **Treatment of adult roundworms (*Toxocara cati*)**



- **Treatment of adult intestinal hookworms** (*Ancylostoma tubaeforme*)



#### **Dogs:**

- **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 cats that are suffering from concomitant disease, or are debilitated and underweight (for size and 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 animals 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 medicinal 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 cats and 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 cats and 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**

Cats:

|  |   |
|--|---|
| Rare<br>(1 to 10 animals / 10,000 animals treated):                            | Application site alopecia (hair loss) <sup>1,2</sup><br>Application site hair changes <sup>3</sup><br>Hypersalivation (increased salivation) <sup>6</sup> |
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Application site irritation <sup>2,4</sup><br>Neurological signs (including seizures) <sup>5</sup>  |

Dogs:

|  |  |
|--|--|
| Rare<br>(1 to 10 animals / 10,000 animals treated):                            | Application site hair changes <sup>3</sup>           |
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Neurological signs (including seizures) <sup>5</sup> |

<sup>1</sup>Mild and transient.

<sup>2</sup>Normally self-resolving, but symptomatic therapy may be applicable in some circumstances

<sup>3</sup>Local temporary clumping of the hair 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.

<sup>4</sup>Transient and focal.

<sup>5</sup>Reversible as with other macrocyclic lactones.

<sup>6</sup>If significant licking occurs, may be observed for a brief period.

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:

| Cats (kg)  | Pipette cap colour | Selamectin (mg)                     | Potency (mg/ml) | Volume (nominal tube size – ml)     |
|--|--------------------|-------------------------------------|-----------------|-------------------------------------|
| ≤2.5   | Pink               | 15                                  | 60              | 0.25                                |
| For cats >2.5 kg, please consider appropriate pipette: |                    |                                     |                 |                                     |
| 2.6-7.5  | Turquoise          | 45                                  | 60              | 0.75                                |
| 7.6-10.0   | Warm grey          | 60                                  | 60              | 1.0                                 |
| >10  | /                  | Appropriate combination of pipettes | /               | Appropriate combination of pipettes |

| Dogs (kg)  | Pipette cap colour | Selamectin (mg)                     | Potency (mg/ml) | Volume (nominal tube size – ml)     |
|--|--------------------|-------------------------------------|-----------------|-------------------------------------|
| ≤2.5   | Pink               | 15                                  | 60              | 0.25                                |
| For dogs >2.5 kg, please consider appropriate pipette: |                    |                                     |                 |                                     |
| 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 |

### Flea treatment and prevention (cats and dogs)



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 (cats and dogs)**



The need for treatment should be determined by the prescribing veterinarian and should be based on the local epidemiological situation (see **Special Warnings**). 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 (cats and dogs)**



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

#### **Treatment of biting lice (cats and dogs)**



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

#### **Treatment of ear mites (cats)**



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

#### **Treatment of ear mites (dogs)**



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 hookworm infections (cats)**



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

#### **Treatment of sarcoptic mange (dogs)**



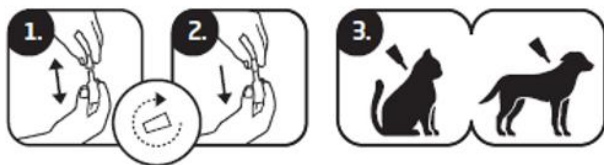
For complete elimination of the mites, a single dose of the veterinary medicinal product should be administered for two consecutive months.

### **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 light and moisture. 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**

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.

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**

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month YYYY}>

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

**16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

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

Tel:

Local representatives and contact details to report suspected adverse events:

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