A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Box 240 mg}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1 x 2 ml
3 x 2 ml
6 x 2 ml
15 x 2 ml

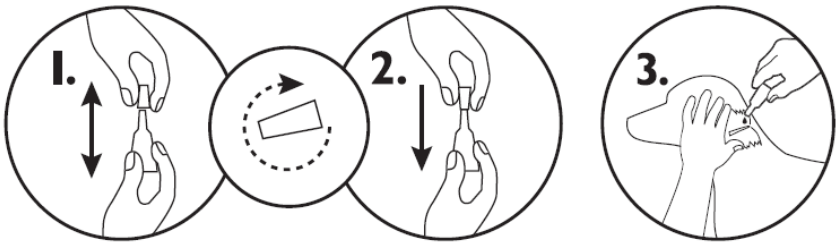
5. TARGET SPECIES

Dogs (20.1–40.0 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

11. SPECIAL STORAGE CONDITIONS

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01656/4148

17. MANUFACTURER'S BATCH NUMBER

Lot

 *Ctenocephalides* spp.

 *Dirofilaria immitis*

 *Otodectes cynotis*

 *Trichodectes canis*

 *Toxocara canis*

Sarcoptes scabiei

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{FOIL LABEL 240 mg}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Selamectin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

240 mg

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

2 ml

4. ROUTE(S) OF ADMINISTRATION

Spot on use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{PIPETTE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Selames 240 mg
Selamectin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

2 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

9. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

PACKAGE LEAFLET:
Selames 30 mg spot-on solution for dogs 2.6–5.0 kg
Selames 60 mg spot-on solution for dogs 5.1–10.0 kg
Selames 120 mg spot-on solution for dogs 10.1–20.0 kg
Selames 240 mg spot-on solution for dogs 20.1–40.0 kg
Selames 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 and manufacturer responsible for batch release:
KRKA d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Selames 30 mg spot-on solution for dogs 2.6–5.0 kg
Selames 60 mg spot-on solution for dogs 5.1–10.0 kg
Selames 120 mg spot-on solution for dogs 10.1–20.0 kg
Selames 240 mg spot-on solution for dogs 20.1–40.0 kg
Selames 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, excipient:

	Concentration of selamectin [mg/ml]	Selamectin [mg]	Volume [ml]	Butylhydroxytoluene (E321) [mg]
Selames 30 mg spot-on solution for dogs 2.6–5.0 kg	120	30	0.25	0.2
Selames 60 mg spot-on solution for dogs 5.1–10.0 kg	120	60	0.5	0.4
Selames 120 mg spot-on solution for dogs 10.1–20.0 kg	120	120	1.0	0.8
Selames 240 mg spot-on solution for dogs 20.1–40.0 kg	120	240	2.0	1.6
Selames 360 mg spot-on solution for dogs 40.1–60.0 kg	120	360	3.0	2.4

Clear, colourless to yellow to brown 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.

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. 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.

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 (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)

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 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 12). 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.

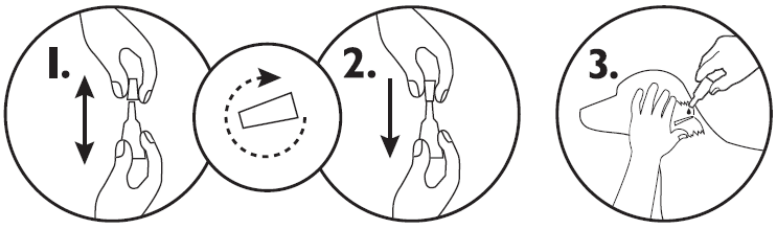
Treatment of ear mites 
A single dose of the veterinary medicinal product should be administered. Loose debris should be gently removed from the external ear canal at the time of treatment. A further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

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:

Remove the pipette from its packaging. Hold the pipette in an upright position, twist and pull the cap off.
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.
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.



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 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 packaging after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

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.

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.

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

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.

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.

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.
Medicines should not be disposed of via wastewater.
Selamectin may adversely affect fish or certain water-borne organisms on which they feed.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2021

15. OTHER INFORMATION

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.

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

Approved 17 April 2023