


FOR EXTERNAL ANIMAL USE ONLY



selamectin and sarolaner

**PROPRIETARY NAME (and dosage form)**  
**REVOLUTION PLUS (spot-on solution)**

Reg. No. G4429 Act 36/1947

**COMPOSITION**

**Qualitative and Quantitative Composition**

Each unit dose (pipette) delivers:


REVOLUTION PLUS spot-on solution	Pipette content (ml)	Selamectin (mg)	Sarolaner (mg)
Cats ≤ 2,5 kg	0,25	15	2,5
Cats > 2,5 – 5 kg	0,5	30	5
Cats > 5 – 10 kg	1	60	10

**Excipients:**  
 0,2 mg/ml butylated hydroxytoluene  
 Dipropylene glycol monomethyl ether  
 Isopropyl alcohol


REVOLUTION PLUS is a clear, colourless to yellow, ready-to-use spot-on solution for cats with, or at risk from mixed parasitic infestations by ticks and fleas, lice, mites, gastrointestinal nematodes or heartworm.

The veterinary medicinal product is exclusively indicated when used against ticks and one or more of the other target parasites is indicated at the same time.


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selamectin and sarolaner/selamectin en sarolaner



selamectin and sarolaner/selamectin en sarolaner



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**Ectoparasites**

- For the treatment and prevention of flea infestations (*Ctenocephalides* spp.). The veterinary medicinal product has immediate and persistent flea killing activity against new infestations for 5 weeks. The product kills adult fleas before they lay eggs for 5 weeks. Through its ovicidal and larvicidal action, the veterinary medicinal product may aid in the control of existing environmental flea infestations to which the animal has access.
- The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).
- Treatment of tick infestations. The veterinary medicinal product has immediate and persistent acaricidal effect for 5 weeks against *Ixodes ricinus* and *Ixodes hexagonus*, and 4 weeks against *Dermacentor reticulatus* and *Rhipicephalus sanguineus*.
- Treatment of ear mites (*Otodectes cynotis*).
- Treatment of biting lice infestations (*Felicola subrostratus*).

Ticks must attach to the host and commence feeding in order to be exposed to sarolaner.

**Nematodes**

- Treatment of adult roundworms (*Toxocara cati*) and adult intestinal hookworms (*Ancylostoma tubaeforme*).
- Prevention of heartworm disease caused by *Dirofilaria immitis* with monthly administration.

The list contains the parasite species tested. This remedy may also be effective against other species. For more information, consult your veterinarian.

**CONTRAINDICATIONS**

Do not use in cats that are suffering from concomitant diseases or are debilitated and underweight (for size and age). Do not use in case of hypersensitivity to the active substances or to any of the excipients.

**STORAGE INSTRUCTIONS**

Store at or below 30 °C.

Do not remove the pipette from the blister until ready to use.

**WARNINGS**

**This product is highly flammable - Keep away from heat, sparks, open flames or other sources of ignition.**

**Special warnings for each target species**

- Use of this veterinary medicinal product is indicated in cats aged at least 8 weeks old and weighing at least 1,25 kg. Ticks need to start feeding on the host to become exposed to sarolaner; therefore, the transmission of infectious tick-borne diseases cannot be excluded.
- 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 recommended that all animals 6 months of age or more should be tested for existing adult heartworm infection before beginning preventive use with the veterinary product.
- This product is not effective against adult *D. immitis*.

**Overdose (symptoms, emergency procedures, antidotes)**

- No clinically significant adverse reactions were observed in kittens from 8 weeks of age treated with up to 5 times the maximum recommended dose of the product for up to 8 consecutive treatments at 28 day intervals, apart from a single cat administered 5 times the maximum dose that displayed transient hypersensitivity to touch, piloerection, mydriasis and mild tremor which resolved without treatment.
- After accidental ingestion of a full product dose, transient gastrointestinal effects such as salivation, soft faeces, emesis, and reduced food consumption may occur, however these should resolve without treatment.
- Keep out of reach of children, uninformed persons and animals.
- This remedy has been extensively tested under a large variety of conditions. Failure thereof may ensue as a result of a wide range of reasons. If this is suspected, seek veterinary advice and contact the registration holder.

**PRECAUTIONS**

**Special precautions to be taken by the person administering the veterinary medicinal product to animals**

- The product is harmful after ingestion. Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product.
- Used pipettes should be disposed of immediately. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
- The product may cause eye irritation. Avoid eye contact including hand-to-eye-contact. Avoid direct contact with treated animals until the application area is dry. 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 attention. People with sensitive skin or known allergy to veterinary medicinal products of this type should handle the veterinary medicinal product with caution.
- Children are not allowed to play with treated cats for 4 hours after treatment.
- It is recommended to treat animals in the evening. On the day of treatment, treated animals should not be permitted to sleep in the same bed as their owner, especially children.

**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 aquatic organisms.
- Containers and residual contents should be disposed of along with collected domestic refuse to avoid contamination of any water sources.
- Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

**ADVERSE REACTIONS**

Use of the veterinary product may result in mild and transient pruritus (itch) at the application site. Mild to moderate alopecia at the application site, erythema and drooling have been uncommonly observed.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment).
- common (more than 1 but less than 10 animals in 100 animals).
- uncommon (more than 1 but less than 10 animals in 1 000 animals).
- rare (more than 1 but less than 10 animals in 10 000 animals).
- very rare (less than 1 animal in 10 000 animals, including isolated reports).

**Use during pregnancy, lactation or lay**

The safety of the veterinary medicinal product has not been established during pregnancy and lactation or in animals intended for breeding. However, selamectin is considered safe for use in breeding, pregnant and lactating cats. While the safety of sarolaner has not been evaluated in breeding, pregnant or lactating cats, laboratory studies with sarolaner in rats and rabbits have not produced any evidence of teratogenic effects. Use only according to the benefit-risk assessment by the prescribing veterinarian.

**Interaction with other medicinal products and other forms of interaction**

During clinical field testing, no interactions between this veterinary medicinal product and routinely used veterinary medicinal products were observed.

**DIRECTIONS FOR USE**

USE ONLY AS DIRECTED

**Spot-on use**

REVOLUTION PLUS should be administered as a single spot-on (topical) application in accordance with the following table (corresponding to a minimum of 6 mg/kg selamectin and 1 mg/kg sarolaner).

Bodyweight of cat (kg)	Pipette content (ml)	Strength and number of pipettes to be administered		
		REVOLUTION PLUS 15 mg/2,5 mg (yellow cap)	REVOLUTION PLUS 30 mg/5 mg (orange cap)	REVOLUTION PLUS 60 mg/10 mg (green cap)
≤ 2,5 kg	0,25 ml	1		
> 2,5 – 5 kg	0,50 ml		1	
> 5 – 10 kg	1,00 ml			1
> 10 kg: Appropriate combination of pipettes				

**APPLICATION**

This veterinary medicinal product is to be applied to the skin surface only.

Do not administer orally or parenterally.

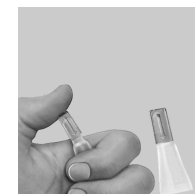
Do not apply when the animal's hair coat is wet.

For ear mite treatment, do not apply directly to the ear canal.

It is important to apply the dose as indicated to prevent the animal from licking and ingesting the product. If significant ingestion occurs, transient gastrointestinal effects such as hyper salivation, emesis, soft faeces or reduced food consumption may be observed and should normally resolve without treatment.

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

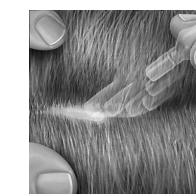
The pipette should be removed from the protective package immediately prior to administration.



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



Part the hair at the base of the cat'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 3 – 4 times to empty the contents in one spot. Avoid contact between the product and your fingers.

Transient cosmetic effects may occur at the application site such as temporary clumping or spiking of the hair, greasiness or dry white deposits, which normally resolve within 24 hours after product application. These effects do not affect the safety or efficacy of the veterinary medicinal product.

**TREATMENT SCHEDULE**

**Fleas and ticks**

For optimal control of tick and flea infestations, the veterinary medicinal product should be administered at monthly intervals and continued throughout the flea and/or tick season based on local epidemiological situations.

Following administration of the product, the adult fleas on the animal are killed within 24 hours, 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.

**Prevention of heartworm disease**

The 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 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 product must be given within a month of the last dose of the former veterinary product.

**Treatment of roundworm and hookworm infections**

A single dose of the product should be administered. The need for and frequency of re-treatment should be in accordance with the advice of the prescribing veterinarian.

**Treatment of biting lice**

A single dose of the product should be administered.

**Treatment of ear mites**

A single dose of the product should be administered. Seek further veterinary examination 30 days after treatment to determine whether a second administration is necessary.

**EFFICACY**

**Pharmacodynamic properties**

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 adult fleas (on the animal), preventing the hatching of flea eggs (on the animal and in its environment) and by killing flea 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. Selamectin is active against adult fleas (*Ctenocephalides* spp.), as well as mites (*Otodectes cynotis*), lice (*Felicola subrostratus*) and gastrointestinal nematodes (*Toxocara cati*, *Ancylostoma tubaeforme*). Activity has also been demonstrated against heartworm (*D. immitis*) larvae.

For fleas, the onset of efficacy is within 24 hours for 5 weeks after product application.

Sarolaner is an acaricide and insecticide belonging to the isoxazoline family. The primary target of action of sarolaner in insects and acarines is functional blockade of ligand-gated chloride channels (GABA-receptors and glutamate-receptors). Sarolaner blocks GABA- and glutamate-gated chloride channels in the central nervous system of insects and acarines. Disruption of these receptors by sarolaner prevent the uptake of chloride ions by GABA- and glutamate-gated ion channels, thus resulting in increased nerve stimulation and death of the target parasite. Sarolaner exhibits higher functional potency to block insect/acarine receptors compared to mammalian receptors. Sarolaner does not interact with known insecticidal binding sites of nicotinic or other GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins, and cyclodiene. Sarolaner is active against adult fleas (*Ctenocephalides* spp.), as well as several tick species such as *Dermacentor reticulatus*, *Ixodes hexagonus*, *Ixodes ricinus*, and *Rhipicephalus sanguineus*. For ticks (*I. ricinus*), the onset of efficacy is within 24 hours of attachment for one month after product application.

**Pharmacokinetic particulars**

Following topical administration of the REVOLUTION PLUS both selamectin and sarolaner are well absorbed with bioavailability mean values of 40,5 % and 57,9 %, respectively and distribute systemically. In cats, selamectin and sarolaner are low clearance compounds with long half-life values, 12,5 days and 41,5 days respectively, following topical administration.

In cats the primary route of selamectin elimination is in faeces and the majority is parent compound. Identification of selamectin metabolites in faeces indicated that metabolic clearance also contributes to the elimination.

The primary route of elimination for sarolaner is biliary elimination of parent sarolaner, with contributions by metabolic clearance.

**Tabulated summary of treatment efficacy duration**

Ectoparasites	Effective in 24 hours for at least 1 month.
Treatment and prevention of Flea infestations: <i>Ctenocephalides felis</i> .	Effective in 24 hours for at least 1 month.
Treatment of Tick infestations: <i>Ixodes ricinus</i> , <i>Ixodes hexagonus</i> , <i>Dermacentor reticulatus</i> , <i>Rhipicephalus sanguineus</i> , <i>Rhipicephalus turanicus</i> , <i>Amblyomma maculatum</i> , <i>Ixodes scapularis</i> , <i>Dermacentor variabilis</i> .	Effective in 24 - 48 hours for at least 1 month. Effective in 48 hours for at least 5 weeks. Effective in 48 hours for at least 35 days. Effective in 48 hours for at least 1 to 2 weeks. Effective in 48 hours for at least 1 month. Effective in 48 hours for at least 1 month. Effective in 48 hours for at least 35 days.
Treatment of Ear mites: <i>Otodectes cynotis</i> .	30 days > 99 % effective
Treatment of biting Lice infestations: <i>Felicola subrostratus</i> .	42 days > 99 % effective

**Nematodes**

Treatment of adult Roundworms: <i>Toxocara cati</i> .	100 % effective
Treatment of adult intestinal Hookworms: <i>Ancylostoma tubaeforme</i> .	> 80 % effective
Prevention of heartworm disease caused by <i>Dirofilaria immitis</i> with monthly administration.	100 % effective

**PRESENTATION**

Translucent polypropylene unit dose pipettes individually packed in aluminium and aluminium/PVC blisters.

The pipette caps are colour-coded as follows:

Pipettes with yellow caps contain 0,25 ml of product and deliver 15 mg selamectin and 2,5 mg sarolaner.

Pipettes with orange caps contain 0,5 ml of product and deliver 30 mg selamectin and 5 mg sarolaner.

Pipettes with green caps contain 1 ml of product and deliver 60 mg selamectin and 10 mg sarolaner.

The product is available in packs of three pipettes (all pipette sizes) and six pipettes (all pipette sizes) placed in cardboard boxes.

Not all pack sizes may be marketed.

**REGISTRATION HOLDER**

Zoetis South Africa (Pty) Ltd  
 Co. Reg. No. 2012/001825/07  
 PostNet Suite 53,  
 Private Bag 9976,  
 Sandton, 2146  
 South Africa  
 Tel. (011) 245 3300 or 0860 ZOETIS (0860 963847)



zoetis Artwork Center: US		AWC Representative		Plant Name / Code	
		K. Minard	JR	Kalamazoo/US60	
QN / Project No.	FG Material No.	New Material No.	Description		
200009342	Multiple	40032419	INS REVOLUTION PLUS		
DIR No. / Version No.	Specification / DWG	Old Material No.	Countries		
511699/00	Z14-800609	N/A	ZA		
Dimensions		Colors			
21.500" x 12.8125" (folds to 5.375" x 2.5625")		<input type="checkbox"/> BLACK <input type="checkbox"/> Deline			
Additional Info.		Version No.	Date		
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SLEGS VIR UITWENDIGE DIEREGBRUIK

# revolution PLUS

selamektien en sarolaner

## EIENDOMSNAAM (en doseervorm)

### REVOLUTION PLUS (op-drup oplossing)

Reg. Nr. G4429 Wet 36/1947

### SAMESTELLING

#### Kwalitatiewe en Kwantitatiewe samestelling

Elke eenheid dosis (pipet) lewer:

#### Aktiewe bestandele:

REVOLUTION PLUS op-drup oplossing	Pipet inhoud (ml)	Selamektien (mg)	Sarolaner (mg)
Katte ≤ 2,5 kg	0,25	15	2,5
Katte > 2,5 – 5 kg	0,5	30	5
Katte > 5 – 10 kg	1	60	10

#### Bymiddels:

0,2 mg/ml gebuileerde hidroksietoloeun

Di-propieleenglukol monometiel eter

Isopropiel alkohol

REVOLUTION PLUS is 'n helder, kleurloos tot geel, gereed-vir-gebruik op-drup oplossing vir katte met, of met 'n risiko van gemengde parasitiese besmettings van bosluise en vlooië, luise, myte, gastro-intestinale rondewurms of hartzurm.

Die veterinêre medisinale produk is eksklusief geïndikeer wanneer gebruik word teen bosluise en een of meer van die ander teiken parasiete soos geïndikeer, op dieselfde tyd.

#### Ektoparasiete

- Vir die behandeling en voorkoming van vlooi besmettings (*Ctenocephalides* spp.). Die veterinêre medisinale produk het 'n onmiddellike en voortdurende vlooidodende aktiwiteit teen nuwe besmettings vir 5 weke. Die produk dood volwasse vlooië voor hul eiers lê vir 5 weke. Deur die eierdodende en larf-dodende aksie, kan die veterinêre medisinale produk help met die beheer van bestaande omgewings vlooi besmettings waartoe die dier toegang het.
- Die produk kan gebruik word as deel van die behandelingsstrategie vir vlooi allergie dermatitis (VAD).
- Behandeling van bosluisebesmettings. Die veterinêre medisinale produk het 'n onmiddellike en voortdurende bosluisedodende effek vir 5 weke teen *Ixodes ricinus* en *Ixodes hexagonus*, en vir 4 weke teen *Dermacentor reticulatus* en *Rhipicephalus sanguineus*.
- Behandeling van oormyte (*Otodectes cynotis*).
- Behandeling van bytende luisebesmettings (*Felicola subrostratus*).

Bosluise moet aan die gasheer heg en met voeding begin om aan sarolaner blootgestel te word.

#### Nematode

- Behandeling van volwasse rondewurms (*Toxocara cati*) en volwasse intestinale haakwurms (*Ancylostoma tubaeforme*).
- Voorkoming van hartzurmsiekte wat veroorsaak word deur *Dirofilaria immitis* deur maandelike toediening.

Die lys bevat die parasiet spesies wat getoets is. Hierdie behandeling kan ook effektief wees teen ander spesies. Vir meer inligting raadpleeg jou veearts.

#### KONTRA-INDIKASIES

Moet nie in katte gebruik word ly aan gepaardgaande siektes, of wat verswak is en ondergewig is nie (vir grootte en ouderdom).

Moet nie gebruik in die geval van hipersensitiewiteit teenoor die aktiewe bestanddeel of enige van die ander bymiddels nie.

#### BERGINGSAAWYSINGS

Berg by of onder 30 °C.

Moenie die pipet verwyder uit die stulpverpakking tot gebruik nie.

#### WAARSKUWINGS

**Hierdie produk is hoogs vlambaar - Hou weg van hitte, vonke, oop vuur en ander bronne van ontbranding.**

#### Spesiale waarskuwings vir elke teiken spesie

- Gebruik van die veterinêre medisinale produk word aanbeveel vir katte wat ten minste 8 weke oud is en ten minste 1,25 kg weeg. Bosluise moet aan die draer voer om aan sarolaner blootgestel te word, daarom kan die oordrag van infektiewe bosluis-oordraagbare siektes nie uitgesluit word nie.
- Hou behandelde diere weg van vure en ander bronne van ontvlaming vir ten minste 30 minute of tot die pels droog is.
- Dit word aanbeveel dat alle diere vanaf 'n 6 maande of ouer ouderdom getoets moet word vir bestaande volwasse hartzurminfeksie voor die aanvang van voorkomende gebruik met die veterinêre produk.
- Hierdie produk is nie effektief teen volwasse *D. immitis* nie.

#### Oordosering (simptome, noodgeval prosedures, teenmiddels)

- Geen kliniese betekenisvolle nuwe-effekte was waargeneem in jong katjies vanaf die ouderdom van 8 weke wat behandel is met tot 5 keer die maksimum aanbevole dosis van die produk tot en met 8 opeenvolgende behandelings met 28 dae intervalle, behalwe vir 'n enkele kat toediening 5 keer die maksimum dosis wat verbygaande hipersensitiewiteit getoon het ten opsigte van aanraking, pilo-ereksie, midriase en matige bewing wat opgelos is sonder behandeling.
- Na toevallige inname van 'n vol produk dosis kan verbygaande gastro-intestinale simptome soos kwyling, sagte ontlasting, braking en verlaagde voedselinname voorkom, maar hierdie behoort op te klaar sonder enige behandeling.
- Hou buite bereik van kinders, oningeligte persone en diere.
- Die middel is breedvoerig onder 'n wye verskeidenheid van toestande getoets, maar dit mag faal as gevolg van verskeie redes. Indien dit vermoed word, raadpleeg 'n veearts en verwittig die registrasiehouer.

#### VOORSORGMATREËLS

**Spesiale voorsorgmaatreëls wat deur die persoon wat die veterinêre medisinale produk aanwend aan diere gevolg moet word**

- Die produk is skadelik na inname. Hou die produk in die oorspronklike verpakking tot gebruik, om te keer dat kinders direkte toegang tot die produk het.
- Gebruikte pipette moet onmiddellik weggegooi word. In die geval van toevallige inname, raadpleeg mediese advies onmiddellik en wys die voubiljet of etiket vir die dokter.

- Die produk kan oog iritasie veroorsaak. Vermoog kontak insluitende hand-tot-oog kontak. Vermoog direkte kontak met behandelde diere tot die aanwendingsarea droog is. Was hande na gebruik en was enige van die produk wat met vel in kontak gekom het onmiddellik af met seep en water. As toevallige oog-blootstelling voorkom, spoel die oog onmiddellik uit met water en soek mediese sorg. Mense met sensitiewe velte of 'n bekende allergie vir veterinêre medisinale produkte van die soort moet die veterinêre medisinale produk versigtig hanteer.
- Kinders moet nie toegelaat word om met behandelde katte te speel tot 4 ure na behandeling nie.
- Dit word aanbeveel om diere te behandel in die aand. Op die dag van behandeling, moet behandelde diere nie toegelaat word om in dieselfde bed as hul eienaar te slaap nie, veral kinders.

#### Spesiale voorsorgmaatreëls vir die verwydering van ongebruikte produkte of afvalmateriaal, indien enige

- Medisyne moet nie verwyder word via afvalwater nie.
- Selamektien kan akwatiese organismes nadelig affekteer.
- Houers en oorblywende inhoud moet saam met versamelde huishoudelike vuilis verwyder word om besoedeling van enige waterbronne te vermy.
- Vra jou veearts of apteker hoe om ontslae te raak van medisyne wat nie meer gebruik word nie. Hierdie maatreëls behoort te help om die omgewing te beskerm.

#### NEWE-EFFEKTE

Gebruik van hierdie veterinêre produk kan lei tot ligte en verbygaande pruritus (jeuk) by die aanwendingsarea. Ligte tot matige haarverlies kan voorkom by die aanwendingsarea, eriteem en kwyling is ongewoon opgemerk.

Die frekwensie van nuwe-effekte word gedefinieer volgens die volgende konvensie:

- baie algemeen (meer as 1 in 10 diere wat nuwe-effekte tydens die duur van een behandeling tye).
- algemeen (meer as 1 maar minder as 10 diere in 100 diere).
- ongewoon (meer as 1 maar minder as 10 diere in 1 000 diere).
- skaars (meer as 1 maar minder as 10 diere in 10 000 diere).
- baie skaars (minder as 1 dier in 10 000 diere, ingesluit geïsoleerde gevalle).

#### Gebruik tydens dragtigheid, laktasie of voortplanting

Die veiligheid van die veterinêre medisinale produk is nog nie bevestig tydens dragtigheid, laktasie of in diere bedoel vir teling nie. Nietemin, selamektien word as veilig beskou vir gebruik in telende, dragtig en lakterende katte. Alhoewel die veiligheid van sarolaner nog nie ge-evalueer is in telende, dragtig of lakterende katte nie, het laboratorium studies getoon dat sarolaner in rotte en hase nie enige teratogeniese effekte veroorsaak het nie. Gebruik slegs volgens die voordeel-risiko assessering deur die voorskrywende veearts.

#### Interaksie met ander medisinale produkte en ander vorme van interaksie

Tydens kliniese veld-evaluasie, was geen interaksies waargeneem tussen hierdie veterinêre medisinale produk en algemeen gebruikte veterinêre medisinale produkte nie.

#### GBRUIKSAANWYSINGS

GBRUIK SLEGS SOOS VOORGESKRYF

#### Op-drup gebruik

REVOLUTION PLUS moet aangewend word as 'n enkel op-drup (topikale) aanwending in ooreenstemming met die volgende tabel (In ooreenstemming met 'n minimum van 6 mg/kg selamektien en 1 mg/kg sarolaner).

Liggaams-gewig van kat (kg)	Pipet inhoud (ml)	Sterkte en hoeveelheid pipette wat toegedien moet word		
		REVOLUTION PLUS 15 mg/2,5 mg (geel propjie)	REVOLUTION PLUS 30 mg/5 mg (oranje propjie)	REVOLUTION PLUS 60 mg/10 mg (groen propjie)
≤ 2,5 kg	0,25 ml	1		
> 2,5 – 5 kg	0,50 ml		1	
> 5 – 10 kg	1,00 ml			1
> 10 kg		Toepaslike kombinasie van pipette		

#### AANWENDING

Die veterinêre medisinale produk moet slegs op die vel oppervlak aangewend word. Moet nie oraal of parenteraal toedien nie.

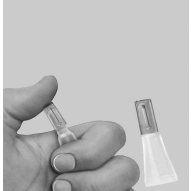
Moet nie aanwend as die dier se pels nat is nie.

Vir oormyt behandeling, moet nie direk in die oorkanaal aanwend nie.

Dit is belangrik om die dosis aan te wend soos aangedui om te verhoed dat die dier lek en die produk inneem. As beduidende inname plaasvind kan verbygaande gastro-intestinale effekte soos verhoogde speekselafskeiding, braking, sagte ontlasting of verlaagde voedsel verbruik waargeneem word en behoort normaal op te klaar sonder behandeling.

Wend aan topikaal op die vel by die basis van die nek voor die skouer blaie.

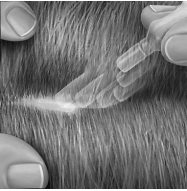
Die pipet moet net voor toediening eers vanuit die beskermende verpakking verwyder word.



Hou die pipet regop en druk die propjie ferm om die toediener seël te breek. Verwyder dan die propjie.



Verdeel die hare by die basis van die kat se nek aan die voorkant van die skouer blaie om 'n klein area van die vel bloot te stel. Wend die punt van die pipet direk op die vel sonder massering.



Druk die pipet ferm 3 - 4 keer om die inhoud te ledig op een plek. Vermoog kontak tussen die produk en jou vingers.

Verbygaande kosmetiese effekte kan voorkom op die aanwendingsarea soos tydelike opeenhoping of punt vorming van die hare, oliërigheid of droë wit aanpaksels, wat normaalweg binne 24 uur van produk aanwending oplos. Die effekte affekteer nie die veiligheid of effektiwiteit van die veterinêre medisinale produk nie.

#### BEHANDELINGSKEDULE

##### Vlooië en bosluise

Vir die optimale beheer van vlooi- en bosluisebesmettings, moet die veterinêre medisinale produk aangewend word in maandelike intervalle en moet gedurig deur die vlooi en/of bosluise seisoen aangewend word gebaseer op lokale epidemiologiese toestande.

Na die aanwending van die produk, sal die volwasse vlooië op die dier binne 24 uur sterf, geen lewensvatbare eiers word geproduseer nie en larwe (wat slegs in die omgewing gevind word) word ook gedood. Hierdie stop vlooi voortplanting, breek die vlooi lewensiklus en kan help met die beheer van bestaande omgewings vlooi besmettings in areas waartoe die dier toegang het.

#### Voorkoming van hartzurmsiekte

Die produk kan aangewend word reg deur die jaar of ten minste binne een maand na die dier se eerste blootstelling aan muskiete en maandeliks daarna tot die einde van die muskiet seisoen. Die finale dosis moet gegee word binne een maand na die laaste blootstelling aan muskiete. As 'n dosis gemis word en 'n maandelike interval tussen dosisse word oorskry, dan moet die produk onmiddellik aangewend word en die maandelike dosering hervat word wat die geleentheid vir die ontwikkeling van volwasse hartzurms sal minimaliseer. Wanneer 'n ander hartzurm-voorkomende produk vervang word in 'n hartzurmsiekte voorkomingsprogram, moet die eerste dosis van die produk toegedien word binne 'n maand van die laaste dosis van die vorige veterinêre produk.

#### Behandeling van rondewurm en haakwurm infeksies

'n Enkele dosis van die produk moet aangewend word. Die behoefte aan en die frekwensie van herbehandling moet wees in ooreenstemming met die advies van die voorskrywende veearts.

#### Behandeling van bytende luise

'n Enkele dosis van die produk moet aangewend word.

#### Behandeling van oormyte

'n Enkele dosis van die produk moet aangewend word. Gaan vir verdere veterinêre ondersoek 30 dae na die behandeling om te bepaal of 'n tweede toediening nodig is.

#### EFFEKTIWITEIT

##### Farmakodinamiese eienskappe

Selamektien is 'n semi-sintetiese samestelling van die avermektien klas. Selamektien verlam en/of dood 'n wye verskeidenheid van ongewerweld parasiete deur in te meng met hul chloried-kanaal geleiding, wat ontwortling van normale neurotransmissie veroorsaak. Hierdie inhibeer die elektriese aktiwiteit van die senuweeselle in nematode en spierselle van geleedpotiges wat lei tot hul verlamming en/of dood.

Selamektien het 'n volwasse dodende, eierdodende en larf-dodende aktiwiteit teen vlooië. Daarom breek dit die lewensiklus van die vlooië effektief deur volwasse vlooië te dood (op die dier), voorkoming van die uitbroei van eiers (op die dier en sy omgewing) en deur larwes te dood (slegs die omgewing). Afval van selamektien-behandelde troeteldiere dood vlooi eiers en larwes wat nie voorheen aan selamektien blootgestel is nie en kan dus help met die beheer van vlooi besmettings in areas waartoe die dier toegang het. Selamektien is aktief teen volwasse vlooië (*Ctenocephalides* spp.) sook myte (*Otodectes cynotis*), luise (*Felicola subrostratus*) en gastro-intestinale nematode (*Toxocara cati*, *Ancylostoma tubaeforme*). Aktiwiteit teen hartzurm (*D. immitis*) larwes was ook gedemonstreer.

Vir vlooië is die aanvang van effektiwiteit binne 24 uur vir 5 weke na produk aanwending.

Sarolaner is 'n mytdoder en insekdoder wat aan die 'isoxazoline' familie behoort. Die primêre teiken van aksie van sarolaner is insekte en myte is funksionele blokkering van ligand-hek chloried kanale (GABA-reseptore en glutamaat-reseptore). Sarolaner blokkeer GABA- en glutamaat-hek chloried kanale in die sentrale senuweestelsel van insekte en myte. Ontwortling van hierdie reseptore deur sarolaner voorkom die opname van chloried-ione deur GABA- en glutamaat-hek loon kanale, wat 'n verhoging in senuwee stimulasie en dood van die teiken parasiet veroorsaak. Sarolaner bewys 'n hoër funksionele neiging om insek/myt reseptore te blokkeer in vergelyking met soogdier reseptore. Sarolaner meng nie met bekende insekdodende bindingsareas of nikotiniëse of ander GABA-ergiese insekdoders soos neonikoteniëoïede, fiprole, milbemisiëne, avermektiëne, en siklodienë nie. Sarolaner is aktief teen volwasse vlooië (*Ctenocephalides* spp.) sowel as verskeie bosluise spesies soos *Dermacentor reticulatus*, *Ixodes hexagonus*, *Ixodes ricinus*, en *Rhipicephalus sanguineus*.

Vir bosluise (*I. ricinus*), is die aanvang van effektiwiteit binne 24 uur van binding vir een maand na produk aanwending.

##### Pharmakokinetiese besonderhede

Na die topikale toediening van REVOLUTION PLUS word beide selamektien en sarolaner goed geabsorbeer met 'n bio-beskikbaarheid gemiddelde waardes van 40,5 % en 57,9 % respektiewelik en word sistemies versprei. In katte is selamektien en sarolaner lae opruiming samestellings met lang half-leef tyd waardes, 12,5 dae en 41,5 dae respektiewelik, na topikale toediening.

In katte is die primêre roete van selamektien eliminasië in ontlasting en die meerderheid is moederbindings. Identifikasie van selamektien metaboliëte in ontlasting dui aan dat metaboliëse opruiming ook bydra tot eliminasië.

Die primêre roete van eliminasië vir sarolaner is biliëre eliminasië van moeder sarolaner, met bydraes deur metaboliëse opruiming.

##### Getabuleerde opsomming van behandeling effektiwiteits duur

Behandeling en voorkoming van Vlooiëbesmettings: <i>Ctenocephalides felis</i> .	Effektief binne 24 uur vir ten minste 1 maand.
Behandeling van Bosluisebesmettings: <i>Ixodes ricinus</i> , <i>Ixodes hexagonus</i> , <i>Dermacentor reticulatus</i> , <i>Rhipicephalus sanguineus</i> , <i>Rhipicephalus turanicus</i> , <i>Amblyomma maculatum</i> , <i>Ixodes scapularis</i> , <i>Dermacentor variabilis</i> .	Effektief binne 24 uur vir ten minste 1 maand. Effektief binne 48 uur vir ten minste 5 weke. Effektief binne 48 uur vir ten minste 1 maand. Effektief binne 48 uur vir ten minste 35 dae. Effektief binne 48 uur vir ten minste 1 - 2 weke. Effektief binne 48 uur vir ten minste 1 maand. Effektief binne 48 uur vir ten minste 1 maand. Effektief binne 48 uur vir ten minste 35 dae.
Behandeling van Oormyte: <i>Otodectes cynotis</i> .	30 dae > 99 % effektief
Behandeling van bytende Luisebesmettings: <i>Felicola subrostratus</i> .	42 dae > 99 % effektief

#### Nematode

Behandeling van volwasse Rondewurms: <i>Toxocara cati</i> .	100 % effektief
Behandeling van volwasse Intestinale Haakwurms: <i>Ancylostoma tubaeforme</i> .	> 80 % effektief
Voorkoming van hartzurmsiekte veroorsaak deur <i>Dirofilaria immitis</i> met maandelike toediening.	100 % effektief

#### AANBIEDING

Deurskynende polipropileen eenheid dosis pipette individueel verpak in aluminium en aluminium/PVC stulpverpakkings.

Die pipet propjies is kleur-gekodeer as volg:

Pipette met geel propjies bevat 0,25 ml van die produk en lewer 15 mg selamektien en 2,5 mg sarolaner.

Pipette met oranje propjies bevat 0,5 ml van die produk en lewer 30 mg selamektien en 5 mg sarolaner.

Pipette met groen propjies bevat 1 ml van die produk en lewer 60 mg selamektien en 10 mg sarolaner.

Die produk is beskikbaar in pakke van 3 pipette (al die pipet groottes) en ses pipette (al die pipet groottes) verpak in karton bokse.

Nie alle verpakkingsgroottes sal bemark word nie.

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