

PACKAGE INSERT (ENGLISH):

For External Animal Use Only

REVOLUTION

For use by or under the control of a veterinarian only

PROPRIETARY NAME(AND DOSAGE FORM):

- 1) Revolution Topical Parasiticide For Puppies and Kittens: Registration no.: G 2819 (Act 36/1947).
- 2) Revolution Topical Parasiticide For Cats: Registration no.: G 2820 (Act 36/1947).
- 3) Revolution Topical Parasiticide For Dogs: Registration no.: G 2821 (Act 36/1947).

INDICATIONS:

REVOLUTION is indicated for the treatment, control and prevention of flea (*Ctenocephalides* spp.) infestations, control of flea allergy dermatitis, treatment and control of ear mites (*Otodectes cynotis*) in dogs and cats and for the treatment and control of sarcoptic mange (*Sarcoptes scabiei*) in dogs. **REVOLUTION** is also indicated for treatment of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infestations in cats and intestinal roundworm (*Toxocara canis* and *Toxascaris leonina*) infestations in dogs. **REVOLUTION** is indicated for the control of tick (*Haemaphysalis leachi* and *Rhipicephalus sanguineus*) infestations in dogs and cats. **REVOLUTION** is also indicated for the treatment of lice infestation in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*). Additionally **REVOLUTION** is indicated for the prevention of heartworm disease by controlling the microfilaria of *Dirofilaria immitis* in dogs and cats. **REVOLUTION** is indicated for litter protection in puppies and kittens against flea and nematode infestations after birth.

CAUTION

STORAGE INSTRUCTIONS:

Store at or below 30 °C (Room Temperature) in the original carton.

PRODUCT DESCRIPTION:

REVOLUTION is a effective broad spectrum endectocide for topical administration to cats and dogs. It contains Selamectin, a semi-synthetic compound of the avermectin class discovered by Pfizer.

REVOLUTION is a colourless to pale yellow, ready to use solution available in a 6% (60 mg/mL of Selamectin) solution for puppies, kittens and cats or a 12% (120 mg/mL of Selamectin) solution for dogs. The product is presented in colour-coded, single dose tubes for topical (dermal) treatment in animals not less than six weeks of age. The content of each tube is formulated to provide a minimum of 6 mg Selamectin/kg body mass.

The compound can be used in ivermectin-sensitive collie dogs and kills a wide range of invertebrate parasites. As a member of the avermectin class it paralyzes and/or kills a wide range of invertebrate parasites through interference with their chloride channel conductance causing disruption of normal neurotransmission. This inhibits electrical activity of nerve/muscle cells in nematodes and arthropods leading to their paralysis and death.

WARNINGS:

Flammable - Keep away from heat, sparks, open flames or other sources of ignition.

May be irritating to skin and eyes. Wash hands after use and wash off any product in contact with the skin immediately with soap and water.

Keep out of reach of children and uninformed persons.

This remedy has been extensively tested under a large variety 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.

First aid:

If poisoning occurs, contact a doctor or Poisons Control Centre. If contact with eyes occurs, then flush eyes copiously with water. In case of ingestion by humans, contact a physician.

DIRECTIONS FOR USE:

1. **For the treatment, control and prevention of flea infestations, control of flea allergy dermatitis, treatment and control of earmites in dogs and cats and for treatment and control of sarcoptic mange in dogs. For treatment of intestinal hookworm and roundworm infestations in cats and intestinal roundworm infestations in dogs. For the treatment of lice infestation in dogs and cats. For the prevention of heartworm disease by controlling the microfilaria of *Dirofilaria immitis* in dogs and cats.**

Apply topically to the skin at the recommended minimum dose of 6 mg Selamectin/kg bodymass once a month.

Do not use on puppies or kittens less than 6 weeks of age.

2. **For the control of tick (*Haemaphysalis leachi* and *Rhipicephalus sanguineus*) infestations in dogs and cats:**

In heavy tick infestations, complete efficacy may not be achieved after the first dose therefore **REVOLUTION** should be administered on a monthly basis with one additional dose administered two weeks after the first dose with monthly dosing continued thereafter.

Do not on puppies or kittens less than 6 weeks of age.

3. **For litter protection in puppies and kittens against flea and nematode infestation after birth.**

Treatment of pregnant and lactating animals to prevent flea infestations and roundworm infection in puppies and kittens:

To prevent flea infestations, **REVOLUTION** should be administered at monthly intervals throughout pregnancy and lactation to bitches and queens. This schedule of treatments will prevent flea infestations in suckling puppies and kittens for seven weeks after birth.

To prevent roundworm infection, **REVOLUTION** should be administered at monthly intervals during pregnancy with a dose administered approximately two weeks before parturition. The next treatment should be administered to the bitch or queen, ten days after parturition and followed by another treatment one month later. This schedule of treatments for bitches and queens will prevent adult roundworm infections in suckling puppies and kittens for seven weeks after birth.

Administer **REVOLUTION** in accordance with the following tables:

For cats and kittens:

Mass (kg)	Package colour	Potency (mg/ mℓ)	Administered volume (nominal tube sizes - mℓ)
Up to 2,5	Mauve	60	0,25
2,6-7,5	Blue	60	0,75
>7,5		60	Appropriate combination of tubes

For dogs and puppies:

Mass (kg)	Package colour	Potency (mg/ mℓ)	Administered volume (nominal tube sizes – mℓ)
Up to 2,5	Mauve	60	0,25
2,6-5,0	Purple	120	0,25
5,1-10,0	Brown	120	0,5
10,1-20,0	Red	120	1,0
20,1-40,0	Teal	120	2,0
>40		120	Appropriate combination of tubes

ADMINISTRATION:

Depress the cap to puncture the seal on the **REVOLUTION** tube; then remove the cap to administer product. Administer the product directly to the skin without massaging into the site. Part the hair on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to empty its entire contents directly onto the skin in one spot. Avoid contact between the product and fingers. Do not apply when the hair coat is wet. Bathing or shampooing the animal 2 or more hours after treatment will not reduce the efficacy of **REVOLUTION**.

Discard the used tubes in the household trash.

Flea Control and Prevention in dogs and cats:

If the animal is already infested with fleas when the first dose of **REVOLUTION** is administered, then adult fleas on the animal are killed and no viable flea eggs are produced after the first application. This stops flea

reproduction. An environmental infestation of fleas may persist for a short time after beginning treatment with **REVOLUTION** because of the emergence of adult fleas from pre-existing pupae. However, large reductions in flea infestations are observable after just one monthly treatment.

For the prevention and lasting control of flea infestations, **REVOLUTION** should be applied at monthly intervals throughout the flea season, starting one month before fleas become active. This ensures that fleas infesting the animal are killed and that no viable flea eggs are produced by these fleas. This breaks the flea life cycle and controls and prevents flea infestations. Results of clinical field efficacy studies using **REVOLUTION** monthly, demonstrated control and prevention of flea infestations and improvement in the clinical signs of flea infestation, including flea allergy dermatitis.

Ear Mite Treatment in dogs and cats:

For the elimination of ear mites (*O. cynotis*), **REVOLUTION** should be applied once as a single dose. A second dose one month after the initial dose of **REVOLUTION** may be required to eliminate mites in some dogs. Monthly use of **REVOLUTION** will treat any subsequent ear mite infestations. Cleansing of the infested ears is recommended to remove the debris.

Sarcoptic Mange Treatment for Puppies and Dogs:

A single dose of **REVOLUTION** is efficacious against natural infestations of *Sarcoptes scabiei* in dogs, however, for complete eradication two doses may be required. Monthly use of **REVOLUTION** will treat any subsequent *Sarcoptes* mite infestations.

Nematode Treatment for Kittens and Cats:

For the treatment of intestinal hookworms (*A. tubaeforme*) and roundworms (*T. cati*), **REVOLUTION** should be applied once as a single treatment. Monthly use of **REVOLUTION** will control hookworm and roundworm infestations.

Nematode Treatment for Dogs:

For the treatment of intestinal roundworms (*T. canis* and *T. leonina*), **REVOLUTION** should be applied twice at monthly intervals. Monthly use of **REVOLUTION** will control roundworm infestations.

Tick Control in Dogs and Cats:

In heavy tick infestations, complete efficacy may not be achieved after the first dose therefore **REVOLUTION** should be administered on a monthly basis with one additional dose administered two weeks after the first dose with monthly dosing continued thereafter.

Lice Treatment in Dogs and Cats:

For the treatment of lice infestation (*Trichodectes canis* and *Felicola subrostratus*) in dogs and cats. **REVOLUTION** should be applied once as a single treatment. Monthly use of **REVOLUTION** will control any subsequent lice infestations.

Heartworm Prevention

A threat exists in the north-eastern parts of the country due to the presence of the mosquito vectors as well as the presence of heartworm disease in the southern parts of Mozambique.

For the prevention of heartworm disease by controlling the microfilaria **REVOLUTION** must be applied on a monthly basis. **REVOLUTION** may be applied year-round or at least within one month after 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 application of **REVOLUTION** and resumption of monthly dosing will minimize the opportunity for the development of adult heartworms. When replacing another heartworm preventive product in a heartworm disease prevention programme, the first dose of **REVOLUTION** must be given within a month of the last dose of the former medication.

REVOLUTION may be safely applied to heartworm infected animals, however, it is recommended, in accordance with good veterinary practice, that all animals ≥ 6 months of age be tested for existing heartworm infections before beginning medication with **REVOLUTION**. It is not effective against adult *D. immitis*; however it may decrease the number of circulating microfilariae.

EFFICACY:

Adult fleas on dogs and cats are killed for one month following administration of **REVOLUTION** according to the recommended dosing schedule. In addition, flea eggs exposed to this **REVOLUTION** dosing schedule are not viable and flea reproduction is stopped. By killing adult fleas, **REVOLUTION** controls signs of flea infestation including flea allergy dermatitis. Ear mites (*O. cynotis*) in dogs and cats, sarcoptic mange mites (*S. scabiei*) in dogs, and intestinal hookworms (*A. tubaeforme*) in cats and roundworms in cats and dogs are

killed after a single dose of **REVOLUTION** and controlled by monthly dosing. **REVOLUTION** should be applied once as a single treatment for lice infestation. Monthly use of **REVOLUTION** will control any subsequent lice infestations. Monthly administration of **REVOLUTION** prevents heartworm disease by controlling the microfilaria of *D. immitis* in dogs and cats. Ticks are killed when engorging on dogs and cats that have been treated with **REVOLUTION**. In heavy tick infestations, complete efficacy may not be achieved after the first dose therefore **REVOLUTION** should be administered on a monthly basis with one additional dose administered two weeks after the first dose with monthly dosing continued thereafter.

PRESENTATION:

REVOLUTION is available in tube sizes for dogs and cats of different mass.

<u>Mass Range</u>	<u>Selamectin</u>	<u>Colour code</u>
up to 2,5 kg	15 mg	Mauve Revolution for Puppies and Kittens
2,6-7,5 kg	45 mg	Blue Revolution for Cats
Revolution for Dogs:		
2,6-5 kg	30 mg	Purple
5,1-10 kg	60 mg	Brown
10,1-20 kg	120 mg	Red
20,1-40 kg	240 mg	Teal

Dogs over 40 kg and cats over 7,5 kg - use appropriate combination of tubes

REGISTRATION HOLDER:

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