



Product Name: BRAVECTO PLUS FLEA, TICK AND WORM 112.5 MG FLURALANER AND 5.6 MG MOXIDECTIN SPOT-ON SOLUTION FOR KITTENS AND SMALL CATS

APVMA Approval No: 85418/113229

Label Name:	BRAVECTO PLUS FLEA, TICK AND WORM 112.5 MG FLURALANER AND 5.6 MG MOXIDECTIN SPOT-ON SOLUTION FOR KITTENS AND SMALL CATS
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Signal Headings:	POISON KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY READ SAFETY DIRECTIONS
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Constituent Statements:	280 mg/mL FLURALANER 14 mg/mL MOXIDECTIN Also contains: 339 mg/mL DIMETHYLACETAMIDE (solvent)
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Claims:	<p>BRAVECTO PLUS provides:</p> <ul style="list-style-type: none">• Treatment and prevention of flea (<i>Ctenocephalides felis</i>) infestations for 3 months.• Treatment and control of paralysis tick (<i>Ixodes holocyclus</i>) for 10 weeks.• Rapid onset of action kills newly emerged adult fleas before they lay eggs.• Reduces incidence of flea allergy dermatitis (FAD) by controlling adult fleas.• For the prevention of heartworm disease caused by <i>Dirofilaria immitis</i> for 2 months.• For the treatment and control of roundworm (immature adults (L5) and adults of <i>Toxocara cati</i> and adults of <i>Toxascaris leonina</i>), and hookworm (4th stage larvae (L4), immature adults (L5) and adults of <i>Ancylostoma tubaeforme</i> and adults of <i>Uncinaria stenocephala</i>).• Treatment and control of ear mites (<i>Otodectes cynotis</i>). <p>EFFICACY</p> <p>BRAVECTO PLUS kills pre-existing and new infestations of paralysis ticks (<i>Ixodes holocyclus</i>) for 10 weeks.</p> <p>BRAVECTO PLUS provides effective control of pre-existing infestations of paralysis ticks (<i>Ixodes holocyclus</i>) within 48 hours.</p> <p>BRAVECTO PLUS provides effective treatment and prevention of fleas on cats for 3 months following application. Fleas are killed by 12 hours after treatment and newly emerged fleas are killed before viable eggs are produced for the entire treatment period. The flea life cycle is broken by the rapid onset of action and the long-lasting efficacy against adult fleas on the cat. Newly emerged adult fleas on a cat are killed before viable eggs are produced.</p> <p>BRAVECTO PLUS reduces incidence of flea allergy dermatitis (FAD) by controlling adult fleas.</p> <p>BRAVECTO PLUS prevents heartworm disease caused by <i>Dirofilaria immitis</i> and treats and controls roundworms and hookworms.</p> <p>BRAVECTO PLUS has been shown to be highly effective against ear mite infestations after a single treatment.</p>
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	<p>Ixodes holocyclus ticks do not occur in Western Australia. In tick season, daily searching for, and removal of, any ticks found is recommended.</p>
Net Contents:	0.4 mL x 1 pipette [2 pipettes, 3 pipettes, 4 pipettes, 6 pipettes] [Illegal to sell pipettes separately]
Directions for Use:	DIRECTIONS FOR USE
Restraints:	
Contraindications:	BRAVECTO PLUS must not be used in case of hypersensitivity to the active constituents or to any of the excipients.
Precautions:	<p>PRECAUTIONS</p> <p>BRAVECTO PLUS should not be used on kittens less than 9 weeks of age or cats weighing less than 1.2 kg.</p>
Side Effects:	Mild and transient skin reactions at the application site may be seen such as flaking skin, itching or hair loss. Shortly after application, the following signs were observed in clinical trials, but were uncommon: breathing discomfort after licking the application site, vomiting, vomiting of blood, diarrhoea, lethargy, hypersalivation, fever, rapid breathing, and dilated pupils.
Dosage and Administration:	See attachment.
General Directions:	<p>General directions NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.</p> <p>MAKE NO ATTEMPT TO REMOVE CAP. CAP DOES NOT COME OFF. TWIST CAP AND USE.</p> <p>Care should be taken to avoid contact with the eyes of the animal. It is recommended not to use directly on skin lesions. This product is for topical use and should not be administered orally. It is important to apply the dose as indicated to prevent the animal from licking and ingesting the product. It is recommended not to allow recently treated animals to groom each other. It is recommended not to allow treated animals to come into contact with untreated animals until the application site is dry. The safety of the veterinary medicinal product has not been established in breeding, pregnant or lactating animals and therefore use in such animals is not recommended. Efficacy after shampooing and wetting has not been assessed.</p> <p>BRAVECTO PLUS contains fluralaner, a member of the antiparasitic class of isoxazoline-substituted benzamide derivatives. Fluralaner acts antagonistically on arthropods ligand-</p>

gated chloride channels (GABA-receptor and glutamate-receptor). BRAVECTO PLUS is effective against fipronil-resistant strains of fleas.

BRAVECTO PLUS also contains moxidectin, a member of the milbemycin group of macrocyclic lactones. Milbemycins mode of action is based on the binding of ligand-gated chloride channels. This leads to an increased membrane permeability of nematode and arthropod nerve and/or muscle cells for chloride ions and results in hyperpolarization, paralysis and death of the parasites. Binding of glutamate-gated chloride channels, which are specific to invertebrates and do not exist in mammals, is considered the main mechanism for the anthelmintic and insecticidal activity.

Both fluralaner and moxidectin are readily systemically absorbed from the topical administration site.

Macrocyclic lactones including moxidectin have been shown to be substrates for p-glycoprotein. Therefore, during treatment with BRAVECTO PLUS, other products that can inhibit p-glycoprotein (e.g. cyclosporine, ketoconazole, spinosad, verapamil) should only be used concomitantly according to the benefit/risk assessment of the responsible veterinarian.

Flea Treatment, Control and Prevention

The average flea life cycle lasts 3 - 8 weeks, and following treatment with Bravecto Plus spot-on the life cycle is broken due to the rapid onset of action and the long-lasting efficacy against adult fleas on the animal and the absence of viable egg production.

The product contributes towards the control of the environmental flea populations in areas to which treated cats have access, by killing newly emerged fleas on a cat before viable eggs are produced.

BRAVECTO PLUS reduces the flea challenge experienced by the animal and aids in the treatment strategy for flea allergy dermatitis.

To obtain maximum flea control, it is recommended that all cats and dogs in the same environment are treated. Cats and dogs may be exposed to fleas when they go outside and they can carry these back into the home.

Heartworm Disease Prevention

To ensure continuous prevention of heartworm disease a repetition of treatment is necessary at 2-month intervals. At the time of treatment BRAVECTO PLUS is effective against *D. immitis* larvae (L3 and L4) which have developed in the previous 30 days and against incoming *D. immitis* larvae (L3 and L4) for the subsequent 60 days.

Prevention of heartworm disease in cats that are only temporarily in endemic areas should start at the latest within 1 month after the first expected exposure to mosquitoes and should be continued at 2-month intervals until return to a non-endemic area.

Fluralaner is part of the isoxazoline family of chemicals. Adverse reactions to this family of chemicals are rarely observed but may include vomiting, diarrhoea, lethargy, inappetence, itching and very rarely, seizures. Most adverse reactions are self-limiting and of short duration. If you have any concerns, please speak to your veterinarian.

Withholding Periods:

Trade Advice:

Safety Directions:

SAFETY DIRECTIONS

Will irritate the eyes. Avoid contact with the eyes. If product in eyes, wash it out immediately with water. Wash hands after use.

First Aid Instructions:

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126. If skin contact occurs, remove contaminated clothing and wash skin thoroughly.

First Aid Warnings:

Additional User Safety:

ADDITIONAL USER SAFETY INFORMATION

Rehandling statements

Do not contact, or allow children to contact the application site until it is dry; it is therefore recommended to treat the animal in the evening. On the day of treatment, treated animals should not be permitted to sleep with their owner, especially children.

Environmental Statements:

Disposal:

Dispose immediately of empty pipette, sachet and carton by wrapping in paper and putting in garbage.

Storage:

Store below 30°C (room temperature).
The pipettes should be kept in the sachet to prevent solvent loss or moisture uptake. The sachets should only be opened immediately prior to use.

Dosage and administration

BRAVECTO PLUS is available in three sizes. The following table indicates the size of pipette to be used according to the body weight of the cat (equivalent to 40 - 94 mg fluralaner/kg body weight and 2 - 4.7 mg moxidectin/kg body weight).

Body weight of cat (kg)	Administration guide: (volume and number of pipettes)		
	112.5 mg fluralaner and 5.6 mg moxidectin for Kittens and Small Cats	250 mg fluralaner and 12.5 mg moxidectin for Medium Cats	500 mg fluralaner and 25 mg moxidectin for Large Cats
	0.4 mL / pipette	0.89 mL / pipette	1.79 mL / pipette
1.2 – 2.8	1		
>2.8 – 6.25		1	
>6.25 – 12.5			1

For cats above 12.5 kg body weight, use a combination of two pipettes that most closely matches the body weight.

Method of administration

Step 1

Immediately before use, open the sachet and remove the pipette. The pipette should be held by base or by the upper rigid portion below the cap in an upright position (tip up) for opening it. The **twist-and-use cap** should be rotated clockwise or counter clockwise one full turn. **The cap will stay on the pipette; it is not possible to remove it.** The pipette is open and ready for application when the breaking of the seal is felt.



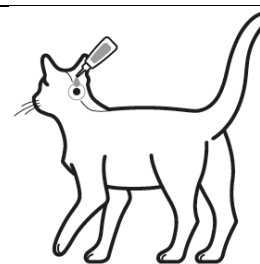
**MAKE NO ATTEMPT TO REMOVE CAP.
CAP DOES NOT COME OFF.
TWIST CAP AND USE.**

Step 2

The cat should be standing or lying with its back horizontal for easy application. Part hair, place the pipette tip on the base of the skull of the cat.

Step 3

Squeeze the pipette gently at least twice and apply the entire contents directly to the cat's skin. The product should be applied on cats up to 6.25 kg body weight in one spot at the base of the skull, or two spots in the middle line of the base of the skull on cats greater than 6.25 kg body weight. Ingestion may cause adverse reactions and will remove product from the coat. If multiple cats are treated and may mutually groom, it is recommended that the cats are separated while product dries.



Treatment schedule

For the treatment and prevention of flea infestation, the product should be administered at intervals of **3 months**.

For the treatment and control of paralysis ticks, the product should be administered at intervals of **10 weeks**.

For the prevention of heartworm disease caused by *Dirofilaria immitis*, the product should be administered at intervals of **2 months**.

One dose of **BRAVECTO PLUS** treats roundworm, hookworm and ear mites and regular dosing with **BRAVECTO PLUS** provides ongoing control of roundworm, hookworm and ear mites. Consult a veterinarian if worm problems persist.

Kittens below six months of age should be weighed regularly. Fast growing kittens that are at risk of outgrowing the initial dose unit weight band during the treatment interval should be retreated at 8-week intervals to ensure persistent flea and tick killing activity and continuous prevention of heartworm disease.

The product should not be administered at intervals shorter than 8 weeks as the safety at shorter intervals has not been tested.

BRAVECTO PLUS can be used year round.

The cat's coat over the treatment application site may appear damp, greasy and mildly clumped.



Product Name: BRAVECTO PLUS FLEA, TICK AND WORM 250 MG FLURALANER AND 12.5 MG MOXIDECTIN SPOT-ON SOLUTION FOR MEDIUM CATS
APVMA Approval No: 85416/113227

Label Name:	BRAVECTO PLUS FLEA, TICK AND WORM 250 MG FLURALANER AND 12.5 MG MOXIDECTIN SPOT-ON SOLUTION FOR MEDIUM CATS
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Signal Headings:	POISON KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY READ SAFETY DIRECTIONS
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Constituent Statements:	280 mg/mL FLURALANER 14 mg/mL MOXIDECTIN Also contains: 339 mg/mL DIMETHYLACETAMIDE (solvent)
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Claims:	<p>BRAVECTO PLUS provides:</p> <ul style="list-style-type: none">• Treatment and prevention of flea (<i>Ctenocephalides felis</i>) infestations for 3 months.• Treatment and control of paralysis tick (<i>Ixodes holocyclus</i>) for 10 weeks.• Rapid onset of action kills newly emerged adult fleas before they lay eggs.• Reduces incidence of flea allergy dermatitis (FAD) by controlling adult fleas.• For the prevention of heartworm disease caused by <i>Dirofilaria immitis</i> for 2 months.• For the treatment and control of roundworm (immature adults (L5) and adults of <i>Toxocara cati</i> and adults of <i>Toxascaris leonina</i>), and hookworm (4th stage larvae (L4), immature adults (L5) and adults of <i>Ancylostoma tubaeforme</i> and adults of <i>Uncinaria stenocephala</i>).• Treatment and control of ear mites (<i>Otodectes cynotis</i>). <p>EFFICACY</p> <p>BRAVECTO PLUS kills pre-existing and new infestations of paralysis ticks (<i>Ixodes holocyclus</i>) for 10 weeks.</p> <p>BRAVECTO PLUS provides effective control of pre-existing infestations of paralysis ticks (<i>Ixodes holocyclus</i>) within 48 hours.</p> <p>BRAVECTO PLUS provides effective treatment and prevention of fleas on cats for 3 months following application. Fleas are killed by 12 hours after treatment and newly emerged fleas are killed before viable eggs are produced for the entire treatment period. The flea life cycle is broken by the rapid onset of action and the long-lasting efficacy against adult fleas on the cat. Newly emerged adult fleas on a cat are killed before viable eggs are produced.</p> <p>BRAVECTO PLUS reduces incidence of flea allergy dermatitis (FAD) by controlling adult fleas.</p> <p>BRAVECTO PLUS prevents heartworm disease caused by <i>Dirofilaria immitis</i> and treats and controls roundworms and hookworms.</p> <p>BRAVECTO PLUS has been shown to be highly effective against ear mite infestations after a single treatment.</p>
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	Ixodes holocyclus ticks do not occur in Western Australia. In tick season, daily searching for, and removal of, any ticks found is recommended.
Net Contents:	0.89 mL x 1 pipette [2 pipettes, 3 pipettes, 4 pipettes, 6 pipettes] [Illegal to sell pipettes separately]
Directions for Use:	DIRECTIONS FOR USE
Restraints:	
Contraindications:	BRAVECTO PLUS must not be used in case of hypersensitivity to the active constituents or to any of the excipients.
Precautions:	BRAVECTO PLUS should not be used on kittens less than 9 weeks of age or cats weighing less than 1.2 kg.
Side Effects:	Mild and transient skin reactions at the application site may be seen such as flaking skin, itching or hair loss. Shortly after application, the following signs were observed in clinical trials, but were uncommon: breathing discomfort after licking the application site, vomiting, vomiting of blood, diarrhoea, lethargy, hypersalivation, fever, rapid breathing, and dilated pupils.
Dosage and Administration:	See attachment. This section contains file attachment.
General Directions:	<p>General directions NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.</p> <p>MAKE NO ATTEMPT TO REMOVE CAP. CAP DOES NOT COME OFF. TWIST CAP AND USE.</p> <p>Care should be taken to avoid contact with the eyes of the animal. It is recommended not to use directly on skin lesions. This product is for topical use and should not be administered orally. It is important to apply the dose as indicated to prevent the animal from licking and ingesting the product. It is recommended not to allow recently treated animals to groom each other. It is recommended not to allow treated animals to come into contact with untreated animals until the application site is dry. The safety of the veterinary medicinal product has not been established in breeding, pregnant or lactating animals and therefore use in such animals is not recommended. Efficacy after shampooing and wetting has not been assessed.</p> <p>BRAVECTO PLUS contains fluralaner, a member of the antiparasitic class of isoxazoline-substituted benzamide derivatives. Fluralaner acts antagonistically on arthropods ligand-gated chloride channels (GABA-receptor and glutamate-receptor). BRAVECTO PLUS is effective against fipronil-resistant strains of fleas.</p>

BRAVECTO PLUS also contains moxidectin, a member of the milbemycin group of macrocyclic lactones. Milbemycins mode of action is based on the binding of ligand-gated chloride channels. This leads to an increased membrane permeability of nematode and arthropod nerve and/or muscle cells for chloride ions and results in hyperpolarization, paralysis and death of the parasites. Binding of glutamate-gated chloride channels, which are specific to invertebrates and do not exist in mammals, is considered the main mechanism for the anthelmintic and insecticidal activity.

Both fluralaner and moxidectin are readily systemically absorbed from the topical administration site.

Macrocyclic lactones including moxidectin have been shown to be substrates for p-glycoprotein. Therefore, during treatment with BRAVECTO PLUS, other products that can inhibit p-glycoprotein (e.g. cyclosporine, ketoconazole, spinosad, verapamil) should only be used concomitantly according to the benefit/risk assessment of the responsible veterinarian.

Flea Treatment, Control and Prevention

The average flea life cycle lasts 3 - 8 weeks, and following treatment with Bravecto Plus spot-on the life cycle is broken due to the rapid onset of action and the long-lasting efficacy against adult fleas on the animal and the absence of viable egg production.

The product contributes towards the control of the environmental flea populations in areas to which treated cats have access, by killing newly emerged fleas on a cat before viable eggs are produced.

BRAVECTO PLUS reduces the flea challenge experienced by the animal and aids in the treatment strategy for flea allergy dermatitis.

To obtain maximum flea control, it is recommended that all cats and dogs in the same environment are treated. Cats and dogs may be exposed to fleas when they go outside and they can carry these back into the home.

Heartworm Disease Prevention

To ensure continuous prevention of heartworm disease a repetition of treatment is necessary at 2-month intervals. At the time of treatment BRAVECTO PLUS is effective against *D. immitis* larvae (L3 and L4) which have developed in the previous 30 days and against incoming *D. immitis* larvae (L3 and L4) for the subsequent 60 days.

Prevention of heartworm disease in cats that are only temporarily in endemic areas should start at the latest within 1 month after the first expected exposure to mosquitoes and should be continued at 2-month intervals until return to a non-endemic area.

Fluralaner is part of the isoxazoline family of chemicals. Adverse reactions to this family of chemicals are rarely observed but may include vomiting, diarrhoea, lethargy, inappetence, itching and very rarely, seizures. Most adverse reactions are self-limiting and of short duration. If you have any concerns, please speak to your veterinarian.

Withholding Periods:

Trade Advice:

Safety Directions:

SAFETY DIRECTIONS

Will irritate the eyes. Avoid contact with the eyes. If product in eyes, wash it out immediately with water. Wash hands after use.

First Aid Instructions:

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126. If skin contact occurs, remove contaminated clothing and wash skin thoroughly.

First Aid Warnings:	
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Additional User Safety:	ADDITIONAL USER SAFETY INFORMATION Rehandling statements Do not contact, or allow children to contact the application site until it is dry; it is therefore recommended to treat the animal in the evening. On the day of treatment, treated animals should not be permitted to sleep with their owner, especially children.
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Environmental Statements:	
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Disposal:	Dispose immediately of empty pipette, sachet and carton by wrapping in paper and putting in garbage.
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Storage:	Store below 30°C (room temperature). The pipettes should be kept in the sachet to prevent solvent loss or moisture uptake. The sachets should only be opened immediately prior to use.
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Dosage and administration

BRAVECTO PLUS is available in three sizes. The following table indicates the size of pipette to be used according to the body weight of the cat (equivalent to 40 - 94 mg fluralaner/kg body weight and 2 - 4.7 mg moxidectin/kg body weight).

Body weight of cat (kg)	Administration guide: (volume and number of pipettes)		
	112.5 mg fluralaner and 5.6 mg moxidectin for Kittens and Small Cats	250 mg fluralaner and 12.5 mg moxidectin for Medium Cats	500 mg fluralaner and 25 mg moxidectin for Large Cats
	0.4 mL / pipette	0.89 mL / pipette	1.79 mL / pipette
1.2 – 2.8	1		
>2.8 – 6.25		1	
>6.25 – 12.5			1

For cats above 12.5 kg body weight, use a combination of two pipettes that most closely matches the body weight.

Method of administration

Step 1

Immediately before use, open the sachet and remove the pipette. The pipette should be held by base or by the upper rigid portion below the cap in an upright position (tip up) for opening it. The **twist-and-use cap** should be rotated clockwise or counter clockwise one full turn. **The cap will stay on the pipette; it is not possible to remove it.** The pipette is open and ready for application when the breaking of the seal is felt.



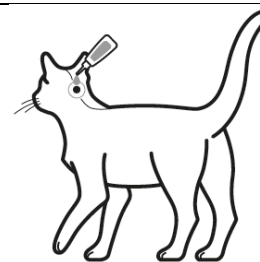
**MAKE NO ATTEMPT TO REMOVE CAP.
CAP DOES NOT COME OFF.
TWIST CAP AND USE.**

Step 2

The cat should be standing or lying with its back horizontal for easy application. Part hair, place the pipette tip on the base of the skull of the cat.

Step 3

Squeeze the pipette gently at least twice and apply the entire contents directly to the cat's skin. The product should be applied on cats up to 6.25 kg body weight in one spot at the base of the skull, or two spots in the middle line of the base of the skull on cats greater than 6.25 kg body weight. Ingestion may cause adverse reactions and will remove product from the coat. If multiple cats are treated and may mutually groom, it is recommended that the cats are separated while product dries.



Treatment schedule

For the treatment and prevention of flea infestation, the product should be administered at intervals of **3 months**.

For the treatment and control of paralysis ticks, the product should be administered at intervals of **10 weeks**.

For the prevention of heartworm disease caused by *Dirofilaria immitis*, the product should be administered at intervals of **2 months**.

One dose of **BRAVECTO PLUS** treats roundworm, hookworm and ear mites and regular dosing with **BRAVECTO PLUS** provides ongoing control of roundworm, hookworm and ear mites. Consult a veterinarian if worm problems persist.

Kittens below six months of age should be weighed regularly. Fast growing kittens that are at risk of outgrowing the initial dose unit weight band during the treatment interval should be retreated at 8-week intervals to ensure persistent flea and tick killing activity and continuous prevention of heartworm disease.

The product should not be administered at intervals shorter than 8 weeks as the safety at shorter intervals has not been tested.

BRAVECTO PLUS can be used year round.

The cat's coat over the treatment application site may appear damp, greasy and mildly clumped.



Product Name: BRAVECTO PLUS FLEA, TICK AND WORM 500 MG FLURALANER AND 25 MG MOXIDECTIN SPOT-ON SOLUTION FOR LARGE CATS
APVMA Approval No: 85413/113224

Label Name:	BRAVECTO PLUS FLEA, TICK AND WORM 500 MG FLURALANER AND 25 MG MOXIDECTIN SPOT-ON SOLUTION FOR LARGE CATS
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Signal Headings:	POISON KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY READ SAFETY DIRECTIONS
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Constituent Statements:	280 mg/mL FLURALANER 14 mg/mL MOXIDECTIN Also contains: 339 mg/mL DIMETHYLACETAMIDE (solvent)
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Claims:	<p>BRAVECTO PLUS provides:</p> <ul style="list-style-type: none">• Treatment and prevention of flea (<i>Ctenocephalides felis</i>) infestations for 3 months.• Treatment and control of paralysis tick (<i>Ixodes holocyclus</i>) for 10 weeks.• Rapid onset of action kills newly emerged adult fleas before they lay eggs.• Reduces incidence of flea allergy dermatitis (FAD) by controlling adult fleas.• For the prevention of heartworm disease caused by <i>Dirofilaria immitis</i> for 2 months.• For the treatment and control of roundworm (immature adults (L5) and adults of <i>Toxocara cati</i> and adults of <i>Toxascaris leonina</i>), and hookworm (4th stage larvae (L4), immature adults (L5) and adults of <i>Ancylostoma tubaeforme</i> and adults of <i>Uncinaria stenocephala</i>).• Treatment and control of ear mites (<i>Otodectes cynotis</i>). <p>EFFICACY</p> <p>BRAVECTO PLUS kills pre-existing and new infestations of paralysis ticks (<i>Ixodes holocyclus</i>) for 10 weeks.</p> <p>BRAVECTO PLUS provides effective control of pre-existing infestations of paralysis ticks (<i>Ixodes holocyclus</i>) within 48 hours.</p> <p>BRAVECTO PLUS provides effective treatment and prevention of fleas on cats for 3 months following application. Fleas are killed by 12 hours after treatment and newly emerged fleas are killed before viable eggs are produced for the entire treatment period. The flea life cycle is broken by the rapid onset of action and the long-lasting efficacy against adult fleas on the cat. Newly emerged adult fleas on a cat are killed before viable eggs are produced.</p> <p>BRAVECTO PLUS reduces incidence of flea allergy dermatitis (FAD) by controlling adult fleas.</p> <p>BRAVECTO PLUS prevents heartworm disease caused by <i>Dirofilaria immitis</i> and treats and controls roundworms and hookworms.</p> <p>BRAVECTO PLUS has been shown to be highly effective against ear mite infestations after a single treatment.</p>
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	<p>Ixodes holocyclus ticks do not occur in Western Australia. In tick season, daily searching for, and removal of, any ticks found is recommended.</p>
Net Contents:	1.79 mL x 1 pipette [2 pipettes, 3 pipettes, 4 pipettes, 6 pipettes]
Directions for Use:	DIRECTIONS FOR USE
Restrains:	
Contraindications:	BRAVECTO PLUS must not be used in case of hypersensitivity to the active constituents or to any of the excipients.
Precautions:	<p>PRECAUTIONS BRAVECTO PLUS should not be used on kittens less than 9 weeks of age or cats weighing less than 1.2 kg.</p>
Side Effects:	Mild and transient skin reactions at the application site may be seen such as flaking skin, itching or hair loss. Shortly after application, the following signs were observed in clinical trials, but were uncommon: breathing discomfort after licking the application site, vomiting, vomiting of blood, diarrhoea, lethargy, hypersalivation, fever, rapid breathing, and dilated pupils.
Dosage and Administration:	This section contains file attachment.
General Directions:	<p>General directions NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.</p> <p>MAKE NO ATTEMPT TO REMOVE CAP. CAP DOES NOT COME OFF. TWIST CAP AND USE.</p> <p>Care should be taken to avoid contact with the eyes of the animal. It is recommended not to use directly on skin lesions. This product is for topical use and should not be administered orally. It is important to apply the dose as indicated to prevent the animal from licking and ingesting the product. It is recommended not to allow recently treated animals to groom each other. It is recommended not to allow treated animals to come into contact with untreated animals until the application site is dry. The safety of the veterinary medicinal product has not been established in breeding, pregnant or lactating animals and therefore use in such animals is not recommended. Efficacy after shampooing and wetting has not been assessed.</p> <p>BRAVECTO PLUS contains fluralaner, a member of the antiparasitic class of isoxazoline-substituted benzamide derivatives. Fluralaner acts antagonistically on arthropods ligand-gated chloride channels (GABA-receptor and glutamate-receptor). BRAVECTO PLUS is effective against fipronil-resistant strains of fleas.</p>

BRAVECTO PLUS also contains moxidectin, a member of the milbemycin group of macrocyclic lactones. Milbemycins mode of action is based on the binding of ligand-gated chloride channels. This leads to an increased membrane permeability of nematode and arthropod nerve and/or muscle cells for chloride ions and results in hyperpolarization, paralysis and death of the parasites. Binding of glutamate-gated chloride channels, which are specific to invertebrates and do not exist in mammals, is considered the main mechanism for the anthelmintic and insecticidal activity.

Both fluralaner and moxidectin are readily systemically absorbed from the topical administration site.

Macrocyclic lactones including moxidectin have been shown to be substrates for p-glycoprotein. Therefore, during treatment with BRAVECTO PLUS, other products that can inhibit p-glycoprotein (e.g. cyclosporine, ketoconazole, spinosad, verapamil) should only be used concomitantly according to the benefit/risk assessment of the responsible veterinarian.

Flea Treatment, Control and Prevention

The average flea life cycle lasts 3 - 8 weeks, and following treatment with Bravecto Plus spot-on the life cycle is broken due to the rapid onset of action and the long-lasting efficacy against adult fleas on the animal and the absence of viable egg production.

The product contributes towards the control of the environmental flea populations in areas to which treated cats have access, by killing newly emerged fleas on a cat before viable eggs are produced.

BRAVECTO PLUS reduces the flea challenge experienced by the animal and aids in the treatment strategy for flea allergy dermatitis.

To obtain maximum flea control, it is recommended that all cats and dogs in the same environment are treated. Cats and dogs may be exposed to fleas when they go outside and they can carry these back into the home.

Heartworm Disease Prevention

To ensure continuous prevention of heartworm disease a repetition of treatment is necessary at 2-month intervals. At the time of treatment BRAVECTO PLUS is effective against *D. immitis* larvae (L3 and L4) which have developed in the previous 30 days and against incoming *D. immitis* larvae (L3 and L4) for the subsequent 60 days.

Prevention of heartworm disease in cats that are only temporarily in endemic areas should start at the latest within 1 month after the first expected exposure to mosquitoes and should be continued at 2-month intervals until return to a non-endemic area.

Fluralaner is part of the isoxazoline family of chemicals. Adverse reactions to this family of chemicals are rarely observed but may include vomiting, diarrhoea, lethargy, inappetence, itching and very rarely, seizures. Most adverse reactions are self-limiting and of short duration. If you have any concerns, please speak to your veterinarian.

Withholding Periods:

Trade Advice:

Safety Directions:

SAFETY DIRECTIONS

Will irritate the eyes. Avoid contact with the eyes. If product in eyes, wash it out immediately with water. Wash hands after use.

First Aid Instructions:

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126. If skin contact occurs, remove contaminated clothing and wash skin thoroughly.

First Aid Warnings:	
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Additional User Safety:	<p>ADDITIONAL USER SAFETY INFORMATION</p> <p>Rehandling statements Do not contact, or allow children to contact the application site until it is dry; it is therefore recommended to treat the animal in the evening. On the day of treatment, treated animals should not be permitted to sleep with their owner, especially children.</p>
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Environmental Statements:	
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Disposal:	Dispose immediately of empty pipette, sachet and carton by wrapping in paper and putting in garbage.
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Storage:	Store below 30°C (room temperature). The pipettes should be kept in the sachet to prevent solvent loss or moisture uptake. The sachets should only be opened immediately prior to use.
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Dosage and administration

BRAVECTO PLUS is available in three sizes. The following table indicates the size of pipette to be used according to the body weight of the cat (equivalent to 40 - 94 mg fluralaner/kg body weight and 2 - 4.7 mg moxidectin/kg body weight).

Body weight of cat (kg)	Administration guide: (volume and number of pipettes)		
	112.5 mg fluralaner and 5.6 mg moxidectin for Kittens and Small Cats	250 mg fluralaner and 12.5 mg moxidectin for Medium Cats	500 mg fluralaner and 25 mg moxidectin for Large Cats
	0.4 mL / pipette	0.89 mL / pipette	1.79 mL / pipette
1.2 – 2.8	1		
>2.8 – 6.25		1	
>6.25 – 12.5			1

For cats above 12.5 kg body weight, use a combination of two pipettes that most closely matches the body weight.

Method of administration

Step 1

Immediately before use, open the sachet and remove the pipette. The pipette should be held by base or by the upper rigid portion below the cap in an upright position (tip up) for opening it. The **twist-and-use cap** should be rotated clockwise or counter clockwise one full turn. **The cap will stay on the pipette; it is not possible to remove it.** The pipette is open and ready for application when the breaking of the seal is felt.



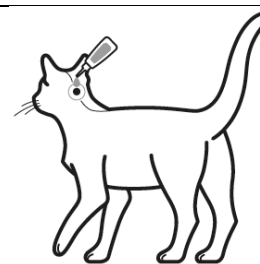
**MAKE NO ATTEMPT TO REMOVE CAP.
CAP DOES NOT COME OFF.
TWIST CAP AND USE.**

Step 2

The cat should be standing or lying with its back horizontal for easy application. Part hair, place the pipette tip on the base of the skull of the cat.

Step 3

Squeeze the pipette gently at least twice and apply the entire contents directly to the cat's skin. The product should be applied on cats up to 6.25 kg body weight in one spot at the base of the skull, or two spots in the middle line of the base of the skull on cats greater than 6.25 kg body weight. Ingestion may cause adverse reactions and will remove product from the coat. If multiple cats are treated and may mutually groom, it is recommended that the cats are separated while product dries.



Treatment schedule

For the treatment and prevention of flea infestation, the product should be administered at intervals of **3 months**.

For the treatment and control of paralysis ticks, the product should be administered at intervals of **10 weeks**.

For the prevention of heartworm disease caused by *Dirofilaria immitis*, the product should be administered at intervals of **2 months**.

One dose of **BRAVECTO PLUS** treats roundworm, hookworm and ear mites and regular dosing with **BRAVECTO PLUS** provides ongoing control of roundworm, hookworm and ear mites. Consult a veterinarian if worm problems persist.

Kittens below six months of age should be weighed regularly. Fast growing kittens that are at risk of outgrowing the initial dose unit weight band during the treatment interval should be retreated at 8-week intervals to ensure persistent flea and tick killing activity and continuous prevention of heartworm disease.

The product should not be administered at intervals shorter than 8 weeks as the safety at shorter intervals has not been tested.

BRAVECTO PLUS can be used year round.

The cat's coat over the treatment application site may appear damp, greasy and mildly clumped.