

NADA Number: 140-915

Trade Name	Interceptor® Interceptor® Flavor Tabs® for Cats Interceptor® Flavor Tabs® SafeHeart™
Sponsor	Novartis Animal Health US, Inc.
Ingredients	Milbemycin Oxime
Species	CATS (DOMESTIC) (Cat, excluding under 6 weeks age) CATS (DOMESTIC) (Cat and kitten, excluding under 1.5 pounds weight) DOGS (Dog, excluding under 2 pounds) DOGS (Dog and puppy, excluding under 4 weeks age)
Routes of Administration	Per Os
Dosage Form	Tablet
Dispensing Status	RX
Patent Number (Expiration Date)	4547520 (No Expiration Date)
Exclusivity	Granted for separate dosage and labeling for cats. Granted for the prescription only use of the product for removal and control of adult <i>Toxocara canis</i> (roundworm) and <i>Trichuris vulpis</i> (whipworm) infections in dogs over 8 weeks of age. The product is currently approved for prevention of heartworm disease caused by <i>Dirofilaria immitis</i> and control of hookworm infections caused by <i>Ancylostoma caninum</i> . Granted for a lower dosage for use in dogs. Treatment of heartworm disease in puppies 4 weeks and older or greater than 2 pounds. Granted for adding a lower dosage for use in the prevention of heartworm disease in dogs and puppies and a new tradename. The original conditions of approval for Interceptor? under NADA 140-915 remain unchanged.
Specifications	Each tablet contains 2.3, 5.75, 11.5, or 23.0 milligrams of milbemycin oxime.
Dosage Amount, Indications & Limitations	<p>Dogs (and puppies)</p> <p>Amount: For hookworm, roundworm, and whipworm, use 0.23 milligram per pound of body weight (0.5 milligram per kilogram). For heartworm, use 0.05 milligram per pound of body weight (0.1 milligram per kilogram).</p> <p>Indications: For prevention of heartworm disease caused by <i>Dirofilaria immitis</i>, control of hookworm infections caused by <i>Ancylostoma caninum</i>, and removal and control of adult roundworm infections caused by <i>Toxocara canis</i> and <i>Toxascaris leonina</i> and whipworm infections caused by <i>Trichuris vulpis</i> in dogs and in puppies 4 weeks of age or greater and 2 pounds of body weight or greater. Limitations: Do not use in puppies less than 4 weeks of age and less than 2 pounds of body weight. Administer once a month. First dose given within 1 month after first exposure to mosquitoes and continue regular use until at least 1 month after end of mosquito season. Federal law restricts this drug to use by or on the order of a licensed veterinarian.</p> <p>Cats (and kittens)</p> <p>Amount: 0.91 milligram per pound of body weight (2.0 milligrams per kilogram).</p> <p>Indications: For prevention of heartworm disease caused by <i>Dirofilaria immitis</i> and the removal of adult <i>Toxocara cati</i> (roundworm) and <i>Ancylostoma tubaeforme</i> (hookworm) infections in cats 6 weeks of age or greater and 1.5 pounds body weight or greater. Limitations: Do not use in kittens less than 6 weeks of age or 1.5 pounds body weight. Administer once a month. Federal law restricts this drug to use by or on the order of a licensed veterinarian.</p>