**INTERCEPTOR (milbemycin oxime)**

**INFORMATION FOR DOSING DOGS**

The palatable once-a-month tablet that prevents heartworm disease, controls adult hookworm, and removes and controls adult roundworm and whipworm infections in dogs and puppies.

**Caution:** Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Keep this and all drugs out of the reach of children.

**Description:** INTERCEPTOR is available in four tablet sizes in color-coded packages for oral administration to dogs and puppies. Each tablet is formulated to provide a minimum of 0.23 mg/lb (0.5 mg/kg) body weight of milbemycin oxime. Milbemycin oxime consists of the oxime derivatives of 5-didehydromilbemycin in the ratio of approximately 80% A4 (C₃₂H₄₅NO₇, MW 555.71) and 20% A₉ (C₁₇H₂₈NO₆, MW 541.68).

**Package color**

<table>
<thead>
<tr>
<th>Color</th>
<th>Milbemycin oxime tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brown</td>
<td>2.3 mg*</td>
</tr>
<tr>
<td>Green</td>
<td>5.75 mg</td>
</tr>
<tr>
<td>Yellow</td>
<td>11.5 mg</td>
</tr>
<tr>
<td>White</td>
<td>22.0 mg</td>
</tr>
</tbody>
</table>

* for dogs only

**Indications:** INTERCEPTOR is indicated for use in the prevention of heartworm disease caused by **Dirofilaria immitis**, the control of adult **Ancylostoma caninum** (hookworm), and the removal and control of adult **Toxocara canis** and **Toxascaris leonina** (roundworms) and **Trichuris vulpis** (whipworm) infections in dogs and in puppies four weeks of age or greater and two pounds body weight or greater.

**Dosage:** INTERCEPTOR is given orally, once a month, at the recommended minimum dosage rate of 0.23 mg milbemycin oxime per pound of body weight (0.5 mg/kg).

**Recommended Dosage Schedule for Dogs**

<table>
<thead>
<tr>
<th>Body Weight</th>
<th>Tablet Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-10 lbs.</td>
<td>One tablet (2.3 mg)</td>
</tr>
<tr>
<td>11-25 lbs.</td>
<td>One tablet (5.75 mg)</td>
</tr>
<tr>
<td>26-50 lbs.</td>
<td>One tablet (11.5 mg)</td>
</tr>
<tr>
<td>51-100 lbs.</td>
<td>One tablet (22.0 mg)</td>
</tr>
</tbody>
</table>

Dogs over 100 lbs. are provided the appropriate combination of tablets.

**Administration:** INTERCEPTOR is palatable and most dogs will consume the tablet willingly when offered by the owner. As an alternative, the dual-purpose tablet may be offered in food or administered as other tablet medications. Watch the dog closely following dosing to be sure the entire dose has been consumed. If it is not entirely consumed, redose once with the full recommended dose as soon as possible.

**INTERCEPTOR must be administered monthly, preferably on the same date each month.** The first dose should be administered within one month of the dog’s first exposure to mosquitoes and monthly thereafter until the end of the mosquito season. If a dose is missed and a 30-day interval between dosing is exceeded, administer INTERCEPTOR immediately and resume the monthly dosing schedule.

If INTERCEPTOR replaces diethylcarbamazine (DEC) for heartworm prevention, the first dose must be given within 30 days after the last dose of DEC.

**Palatability:** Palatability trials conducted in 244 dogs from 10 different U.S. veterinary practices demonstrated that INTERCEPTOR was willingly accepted from the owner by over 95% of dogs. The trial was comprised of dogs representing 60 different breeds and both sexes, with weights ranging from 2.1 lbs. to 143.3 lbs., and ages ranging from 9 weeks to 15 years.

**Precautions:** Do not use in puppies less than four weeks of age or less than two pounds body weight. Prior to initiation of the INTERCEPTOR treatment program, dogs should be tested for existing heartworm infections. Infected dogs should be treated to remove adult heartworms and microfilariae prior to initiating treatment with INTERCEPTOR. Mild, transient hypersensitivity reactions manifested as labeled respiration, vomiting, salivation and lethargy, have been noted in some treated dogs carrying a high number of circulating microfilariae. These reactions are presumably caused by release of protein from dead or dying microfilariae.

**Adverse Reactions:** The following adverse reactions have been reported following the use of INTERCEPTOR: Depression/lethargy, vomiting, ataxia, anorexia, diarrhea, convulsions, weakness and hypersalivation.

**Efficacy:** INTERCEPTOR eliminates the tissue stage of heartworm larvae and the adult stage of hookworm (**Ancylostoma caninum**), roundworms (**Toxocara canis**, **Toxascaris leonina**) and whipworm (**Trichuris vulpis**) infestations when administered orally according to the recommended dosage schedule. The anthelmintic activity of milbemycin oxime is believed to be a result of interference with invertebrate neurotransmission.

**Safety:** Milbemycin oxime has been tested safely in over 75 different breeds of dogs, including collies, pregnant females, breeding males and females, and puppies over two weeks of age. In well-controlled clinical field studies, 786 dogs completed treatment with milbemycin oxime. Milbemycin oxime was used safely in animals receiving frequently used veterinary products such as vaccines, anthelmintics, antibiotics, steroids, flea collars, shampoos, and dips.

Safety studies were conducted in young cats and kittens and doses of 1X, 3X and 5X the minimum recommended dose (2.0 mg/kg) were administered according to the protocol. Tolerable maximum doses at exaggerated doses of 1OX also demonstrated no drug-related adverse effects in kittens and young adult cats.

**How supplied:** INTERCEPTOR is available in three tablet sizes (see Dosage section), formulated according to the weight of the dog. Each tablet size is available in color-coded packages of 6 or 12 tablets each, which are packaged 10 per display carton.

**Storage conditions:** INTERCEPTOR should be stored at room temperature, between 59° and 77°F (15-25°C).

**INFORMATION FOR DOSING CATS**

The palatable once-a-month tablet that prevents heartworm disease and removes adult roundworms and hookworms in cats and kittens.

**Caution:** Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Keep this and all drugs out of the reach of children.

**Description:** INTERCEPTOR is available in three tablet sizes in color-coded packages for oral administration to cats and kittens. Each tablet is formulated to provide a minimum of 0.9 mg/lb (2.0 mg/kg) body weight of milbemycin oxime. Milbemycin oxime consists of the oxime derivatives of 5-didehydromilbemycin in the ratio of approximately 80% A₉ (C₁₇H₂₈NO₆, MW 555.71) and 20% A₉ (C₁₇H₂₈NO₆, MW 541.68).

**Indications:** INTERCEPTOR is indicated for use in the prevention of heartworm disease caused by **Dirofilaria immitis**, and the removal of adult **Ancylostoma tubaeforme** (hookworm) and **Toxocara cati** (roundworm) in cats and kittens six weeks of age or greater and 1.5 lbs. body weight or greater.

**Dosage:** INTERCEPTOR for Cats is given orally, once a month, at the recommended minimum dosage rate of 0.9 mg milbemycin oxime per pound of body weight (2.0 mg/kg).

**Recommended Dosage Schedule for Cats**

<table>
<thead>
<tr>
<th>Body Weight</th>
<th>Tablet Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5 to 6 lbs.</td>
<td>One tablet (5.75 mg)</td>
</tr>
<tr>
<td>6.1 to 12 lbs.</td>
<td>One tablet (11.5 mg)</td>
</tr>
<tr>
<td>12.1 to 25 lbs.</td>
<td>One tablet (22.0 mg)</td>
</tr>
</tbody>
</table>

Cats over 25 lbs. are provided the appropriate combination of tablets.

**Administration:** INTERCEPTOR for Cats is palatable and may be offered by the owner as a treat. As an alternative, the tablet may be offered in food or administered as other tablet medications. The tablets can be broken for ease of administration. Watch the cat closely following dosing to be sure the entire dose has been consumed. If it is not entirely consumed, redose once with the full recommended dose as soon as possible.

**INTERCEPTOR for Cats must be administered monthly, preferably on the same date each month.** The first dose should be administered within one month of the cat’s first exposure to mosquitoes and monthly thereafter until the end of the mosquito season. If a dose is missed and a 30-day interval between dosing is exceeded, administer INTERCEPTOR for Cats immediately and resume the monthly dosing schedule. It is recommended that cats be tested for existing heartworm infection prior to starting treatment with INTERCEPTOR for Cats (see Precautions).

**Palatability:** Palatability trials conducted in 72 cats demonstrated that cats were successfully dosed with INTERCEPTOR for Cats by the owner when they either offered the tablet as a treat, placed the tablet in the cat’s mouth or placed the tablet in the cat’s food in 72% of cats. About 16% of the cats were dosed manually and 13% of the cats were not successfully dosed according to the protocol.

**Precautions:** Do not use in kittens less than six weeks of age or less than 1.5 lbs. body weight. Safety studies in heartworm-positive cats has not been established. Safety in breeding, pregnant, and lactating queens and breeding tans has not been established.

**Efficacy:** INTERCEPTOR for Cats eliminate the tissue stage of heartworm larvae and hookworm (**Ancylostoma tubaeforme**) and roundworm (**Toxocara cati**) infections when administered orally according to the recommended dosage schedule. The anthelmintic activity of milbemycin oxime is believed to be a result of interference with invertebrate neurotransmission.

**Safety:** Milbemycin oxime has been tested safely in over 8 different breeds of cats. In well-controlled clinical field studies 141 cats completed treatment with milbemycin oxime. Milbemycin oxime was used safely in animals receiving frequently used veterinary products such as vaccines, anthelmintics, antibiotics, steroids, flea collars, shampoos and dips.

Safety studies were conducted in young cats and kittens and doses of 1X, 3X and 5X the minimum recommended dose (0.2 mg/kg) were administered according to the protocol. Tolerable maximum doses at exaggerated doses of 1OX also demonstrated no drug-related adverse effects in kittens and young adult cats.

**How supplied:** INTERCEPTOR for Cats is available in three tablet sizes (see Dosage section), formulated according to the weight of the cat. Each tablet size is available in color-coded packages of 6 or 12 tablets each, which are packaged 10 per display carton.

**Storage conditions:** INTERCEPTOR for Cats should be stored at room temperature, between 59° and 77°F (15-25°C).

**Manufactured for:** Elanco US Inc.
Greenfield, IN 46140, USA

NADA #140-915, Approved by FDA

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