INTERCEPTOR™ PLUS (milbemycin oxime/praziquantel)

Caution
Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Description
INTERCEPTOR PLUS is available in four strengths in color-coded packages for oral administration to dogs and puppies according to their weight. Each chewable flavored tablet is formulated to provide a minimum of 0.23 mg/pound (0.5 mg/kg) of milbemycin oxime and 2.28 mg/pound (5 mg/kg) of praziquantel.

Milbemycin oxime consists of the oxime derivatives of 5-dehydrodimelbemycin in the ratio of approximately 80% A<sub>1</sub> (C<sub>9</sub>H<sub>11</sub>N<sub>2</sub>O<sub>4</sub>, MW 555.71) and 20% A<sub>2</sub> (C<sub>9</sub>H<sub>12</sub>N<sub>2</sub>O<sub>4</sub>, MW 541.68). Milbemycin oxime is classified as a macrocyclic lactam.

Praziquantel is an isoquinolinedione anthelmintic with the chemical name 2-(1,2-Cyclohexylcarboxyl)-1,2,3,6,7,11b-hexahydro-4H-pyrazino[2,1-a]isoquinolin-4-one.

Indications
INTERCEPTOR PLUS is indicated for the prevention of heartworm disease caused by Dirofilaria immitis, and for the treatment and control of adult roundworm (Toxocara canis, Toxascaris leonina), adult hookworm (Ancylostoma caninum), adult whipworm (Trichuris vulpis), and adult tapeworm (Taenia pisiformis, Echinococcus multilocularis, Echinococcus granulosus, and Dipylidium caninum) infections in dogs and puppies two pounds of body weight or greater and six weeks of age or older.

Dosage and Administration
INTERCEPTOR PLUS should be administered orally, once every month, at the minimum dosage of 0.23 mg/lb (0.5 mg/kg) of milbemycin oxime, and 2.28 mg/lb (5 mg/kg) of praziquantel. For heartworm prevention, give once monthly for at least 6 months after exposure to mosquitoes (see EFFECTIVENESS).

<table>
<thead>
<tr>
<th>Body Weight</th>
<th>Milbemycin Oxime per chewable</th>
<th>Praziquantel per chewable</th>
<th>Number of chewables</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 to 8 lbs.</td>
<td>2.3 mg</td>
<td>22.8 mg</td>
<td>One</td>
</tr>
<tr>
<td>8.1 to 25 lbs.</td>
<td>5.75 mg</td>
<td>57 mg</td>
<td>One</td>
</tr>
<tr>
<td>25.1 to 50 lbs.</td>
<td>11.5 mg</td>
<td>114 mg</td>
<td>One</td>
</tr>
<tr>
<td>50.1 to 100 lbs.</td>
<td>23 mg</td>
<td>228 mg</td>
<td>One</td>
</tr>
<tr>
<td>Over 100 lbs.</td>
<td>Administer the appropriate combination of chewables.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

INTERCEPTOR PLUS may be offered to the dog by hand or added to a small amount of dog food. The chewables should be administered in a manner that encourages the dog to chew, rather than to swallow without chewing. Chewables may be broken into pieces and fed to dogs that normally swallow treats whole. Care should be taken that the dog consumes the complete dose, and treated animals should be observed for a few minutes after administration to ensure that no part of the dose is lost or rejected. If it is suspected that any of the dose has been lost, redosing is recommended.

Heartworm Prevention
INTERCEPTOR PLUS should be administered at monthly intervals beginning within 1 month of the dog's first seasonal exposure to mosquitoes and continuing until at least 6 months after the dog's last seasonal exposure (see EFFECTIVENESS). INTERCEPTOR PLUS may be administered year-round without interruption. When switching from another heartworm preventative product to INTERCEPTOR PLUS, the first dose of INTERCEPTOR PLUS should be given within a month of the last dose of the former product.

Intestinal Nematode and Cestode Treatment and Control
Dogs may be exposed to and can become infected with roundworms, whipworms, hookworms, and tapeworms throughout the year, regardless of season or climate. Clients should be advised of appropriate measures to prevent reinfection of their dog with intestinal parasites. Because the prepatent period for E. multilocularis may be as short as 26 days, dogs treated at the labeled monthly intervals may become reinfected and shed eggs between treatments.

Contraindications
There are no known contraindications to the use of INTERCEPTOR PLUS.

Warnings
Not for use in humans. Keep this and all drugs out of the reach of children.

Precautions
Treatment with fewer than 6 monthly doses after the last exposure to mosquitoes may not provide complete heartworm prevention (see EFFECTIVENESS). Prior to administration of INTERCEPTOR PLUS, dogs should be tested for existing heartworm infections. At the discretion of the veterinarian, infected dogs should be treated to remove adult heartworms. INTERCEPTOR PLUS is not effective against adult D. immitis, Mild, transient hypersensitivity reactions, such as labored breathing, vomiting, hyperventilation, and lethargy, have been noted in some dogs treated with milbemycin oxime carrying a high number of circulating microfilariae. These reactions are presumably caused by release of protein from dead or dying microfilariae. Do not use in puppies less than six weeks of age.

How Supplied
INTERCEPTOR PLUS is available in four strengths, formulated according to the weight of the dog. Each strength is available in color-coded packages of six chewable tablets each. The tablets containing 2.3 mg milbemycin oxime/22.8 mg praziquantel or 0.75 mg milbemycin oxime/57 mg praziquantel are also available in color coded packages of one chewable tablet each. Manufactured for: Elanco US Inc.

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