DIROBAN®
(melarsomine dihydrochloride)

STERILE POWDER FOR INJECTION
An effective and convenient treatment for canine heartworm disease

INDICATIONS
Heartworm Disease Classification:
CLASS 1: Only moderate laboratory and radiographic signs and be categorized as Class 1.
CLASS 2: Significant laboratory or radiographic alterations or they may have significant clinical signs with
D. immitis

Pharmacology:
Exercise restriction are recommended. Other supportive therapies should be considered on a case-

Special Considerations for Older Dogs:
several weeks up to 1 month.

DIROBAN is contraindicated in dogs with very severe (Class 4) heartworm disease. Patients in this
classification will have no objective radiographic or other abnormal laboratory parameters will be present.

Active Ingredient:
Canine Heartworm Treatment

Dosage and Administration:
The dogs were dosed at 2.5 and 5.0 mg/kg (1X and 2X the
injection and persisted from 1 to 72 days (average 30 days), was the most common clinical observa-
tion. In one dog, the initial dose was administered intravenously but the rest were given intramuscularly
in the lumbar (L3 - L5) muscles. The dogs were dosed at 2.5 and 5.0 mg/kg (1X and 2X the
recommended dosing), and the adverse reactions were observed for 24 hours of injection. The
dog vomited once and the diarrhea resolved within 24 hours. The third

Clinical observations/adverse reactions occurring in less than 1.5% of the dogs treated with melarsomine dihydrochloride include: abdominal hemorrhage, abdominal pain, bloody stool/diarrhea, colitis, gingivitis, pancreatitis, anemia, DIC, hemoglobinemia, icterus (mucous membranes), discolored urine, hematuria, inappropriate urination, low specific gravity, polyuria, pyuria, bronchitis, miscellaneous

Adverse Events:
The following table enumerates adverse events that occurred in 1.5% or more of dogs with Class 1, 2, and
3. The onset times of the most common reactions in clinical trials were as follows:

<table>
<thead>
<tr>
<th>Clinical Observation/Adverse Reaction</th>
<th>Average Onset Time in Days</th>
<th>With Ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swelling/Edema/Seroma</td>
<td>3.2</td>
<td>3.2 - 3.4</td>
</tr>
<tr>
<td>Injection Site Reactions</td>
<td>32.8</td>
<td>3.2 - 68</td>
</tr>
</tbody>
</table>

Post-treatment depression/lethargy, anorexia/inappetence, and vomiting than younger dogs.

Clinical observations include tremors, lethargy, unsteadiness/ataxia, restlessness, panting, shallow and labored respiration, rales, severe salivation, and vomiting which

It is vital to classify the severity of heartworm disease to apply the appropri-

Laboratory Studies:
The sensitivity of serum cardiac antigen tests were used

Conversion Rate:
The conversion rate ranged from 89.7 to 98.2% after two treatment

TREATMENT RECORD
1. Determine the clinical classification of the dog. 

After diagnosing heartworm disease with an in-office antigen test kit and/or detection of microfilariae, determine the Class of disease as follows:

**Heartworm Disease classification**

<table>
<thead>
<tr>
<th>Class 1</th>
<th>Class 2</th>
<th>Class 3</th>
<th>Class 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asymptomatic to Mild Canine Heartworm Disease</td>
<td>Moderate Canine Heartworm Disease</td>
<td>Severe Canine Heartworm Disease</td>
<td>Very Severe Canine Heartworm Disease</td>
</tr>
<tr>
<td>Few signs or no specific lesions; good prognosis. Give DIROBAN and rest twice 24 hours apart.</td>
<td>Few signs or not optimal lesions; good to fair prognosis. Give DIROBAN and rest twice 24 hours apart.</td>
<td>Few signs or not optimal lesions; guarded prognosis. Give DIROBAN &amp; rest twice 24 hours apart.</td>
<td>Canine syndrome; very guarded prognosis. See contraindications on package insert.</td>
</tr>
</tbody>
</table>

**Objective Assessment**

<table>
<thead>
<tr>
<th>Class 1</th>
<th>Class 2</th>
<th>Class 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO CLINICAL SIGNS</td>
<td>FAINT, GENTLE LOSS OF CONDITION</td>
<td>CARDIAC CACHESIA</td>
</tr>
<tr>
<td>FATIGUE ON EXERCISE</td>
<td>PERSISTENT COUGH</td>
<td>REFRACTORY PULMONARY ARTERY ENGORGEMENT</td>
</tr>
<tr>
<td>OCCASIONAL COUGH</td>
<td>DYSPEPSIA</td>
<td>RIGHT-SIDE FAILURE (ANGLES AND/OR JUGULAR PULSE)</td>
</tr>
</tbody>
</table>

2. Heartworm disease classification

- 1A or 2A and 1B
- 1A or 2A and 2B
- 2A or 3A and 3B
- OR 3A and 2B

3. Determine the appropriate treatment and the prognosis

**Class 1**

- Asymptomatic to Mild Canine Heartworm Disease
- Few signs or no specific lesions; good prognosis
- Give DIROBAN and rest twice 24 hours apart
- 2.5 mg/kg body weight

**Class 2**

- Moderate Canine Heartworm Disease
- Few signs or not optimal lesions; good to fair prognosis
- Give DIROBAN and rest twice 24 hours apart
- 2.5 mg/kg body weight

**Class 3**

- Severe Canine Heartworm Disease
- Few signs or not optimal lesions; guarded prognosis
- Give DIROBAN & rest twice 24 hours apart
- 2.5 mg/kg body weight

4. Carefully weigh the dog

The exact weight of the dog is __________ lb.

To convert weight in lb to kg, divide weight in lb by __________.

5. Prepare the injectable solution

Prepare a 2.5% injectable solution by adding 2 mL water for injection supplied with each 50 mg vial of DIROBAN.

6. Determine the volume per administration

<table>
<thead>
<tr>
<th>WEIGHT (lb)</th>
<th>VOLUME (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2</td>
<td>0.50</td>
</tr>
<tr>
<td>2.1-4</td>
<td>0.75</td>
</tr>
<tr>
<td>4.1-8</td>
<td>1.25</td>
</tr>
<tr>
<td>8.1-14</td>
<td>2.50</td>
</tr>
<tr>
<td>14.1-24</td>
<td>4.00</td>
</tr>
<tr>
<td>24+</td>
<td>8.00</td>
</tr>
</tbody>
</table>

7. Select the proper needle size for injection

- Less than 22 lbs (10 kg) dogs use 23 gauge 1 inch needle
- Greater than 22 lbs (10 kg) dogs use 22 gauge 1 ½ inch needle

8. Lumbar injection site location and record

**Do not administer in any other site.**

- Warning: Deep intramuscular injection in the middle of the lumbar (epaxial) musculature in the 3rd through 5th lumbar region only. Avoid subcutaneous injection and/or leakage. Use alternating sides with each administration. (see SAFETY section of the Package Insert.)
- The injection should be mid-muscle, avoiding nerve roots.

9. Administer preventives consistent with product label instructions and re-exposure risks

- Microfilaricidal treatment should be evaluated.

10. Retest with in-office antigen test in 4 months

- Result: **Antigen**

  - **Positive**: Retreatment can be elected taking into consideration the condition, age and use of the dog. Worms that were too young to be killed by the first series, i.e., <4 months, may be killed by a second treatment series.