Cerestat Artwork Center: 15

**Cerestat Injectable**

**Anticipated**

For management of gastrointestinal signs in dogs and cats.

**WARNING**


**DESCRIPTION**

Cerestat Injectable Solution is indicated for the prevention and treatment of acute vomiting in dogs.

**Adverse Reactions**

The following adverse reactions were reported in dogs treated with CERENIA Injectable Solution:

### Dogs:

- **Clinical signs**:
  - Anorexia
  - Lethargy
  - Tremors
  - Fever
  - Dyspnea
  - Collapse/loss of consciousness

- **Pathologic findings**:
  - Bone marrow hypocellularity
  - Hypersalivation

### Cats:

- **Clinical signs**:
  - Anorexia
  - Lethargy

Pharmacokinetics:

**Cerestat Injectable Solution**

**Pharmacokinetic Parameters in Beagle Dogs**

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<tr>
<td>1 mg/kg PO</td>
<td>102.99±46.06</td>
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<tr>
<td>1 mg/kg IV</td>
<td>257.84±49.95</td>
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<td>351.34±53.65</td>
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**Pharmacokinetic Parameters in Domestic Shorthair Cats**

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**Cerestat Injectable Solution**

**Agents: For Prevention of Vomiting in Dogs 4 months of Age and Older**

**treatment with CERENIA Injectable Solution. Thereafter, CERENIA Solution intravenously over 1-2 minutes or subcutaneously at 1 mg/kg**

**Adverse reactions seen in a European field study included ataxia, tremors, fever, dyspnea, collapse/loss of consciousness, vomiting in dogs treated with CERENIA Injectable Solution. The following adverse reactions were reported in domestic shorthair cats treated with CERENIA Injectable Solution:**

### Cats:

- **Clinical signs**:
  - Anorexia
  - Lethargy

**Post-Approval Experience (Rev. 2015)**

**Pharmacokinetics**

**Cerestat Injectable Solution**

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Solution subcutaneously and/or CERENIA Tablets at a minimum of 15 minutes and seek medical attention.

If accidental skin exposure, wash with soap and water. CERENIA is also known to elicit localized allergic skin reactions in some individuals.

Injectable Solution.

In a study of ordinary cancer patients, dogs were treated with CERENIA Injectable Solution or placebo after 1 hour prior to the administration of the chemotherapy. Bone marrow hypocellularity was observed at higher frequency and decreased in 28% of dogs treated with CERENIA Injectable Solution and 4% (2/46) of dogs treated without placebo. Bone marrow hypocellularity was observed at 20% of all days treated with placebo.

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The underlying cause of acute vomiting should be identified and treated before any consideration is given to the treatment of the vomiting itself. In the absence of evidence of the potential causation of vomiting, CERENIA Injectable Solution or Tablets may be used for the prevention of acute vomiting at 2 mg/kg (PO). Urinary recovery of maropitant and its major metabolites was 9.4% and 13%, respectively, on Day 11, compared to 19.9% and 16.6%, respectively, on Day 12. The mean half-life of elimination of maropitant in dogs was 36 hours, compared to 17.2 hours in adults. The mean bioavailability of the subcutaneously administered maropitant was 82% in adults and 84% in dogs. The mean half-life of elimination of maropitant in dogs was 36 hours, compared to 17.2 hours in adults. The mean bioavailability of the subcutaneously administered maropitant was 82% in adults and 84% in dogs.

The following adverse reactions were reported in 77 dogs treated with CERENIA Injectable Solution and Tablets: Pain/vocalization upon injection, depression/lethargy, and injection site soreness in one dog treated with CERENIA Injectable Solution or Tablets.

The following adverse events reported for dogs are listed in the adverse events section of the label, as well as those listed in the following sections: Gastrointestinal (nausea, vomiting, diarrhea, anorexia, constipation, abnormal stools, feces pH and consistency, increased and decreased appetite, abnormal oral/nasal/oropharyngeal secretions, abdominal pain, hemorrhagic vomiting), Behavioral (self-mutilation, ataxia, incontinence, abnormal walking pattern, vocalization upon injection, dyspnea, ataxia, fever, recumbency, seizures, food refusal, and multifocal pain), Genitourinary (hematuria, abnormal urination, anuria, elevated urinalysis parameters including proteinuria, hematuria, and pyuria), and miscellaneous (weight loss, increased and decreased body temperature, increased and decreased heart rate, lymphadenopathy, pyrexia, decreased and increased liver enzymes, mouth ulcers, and cutaneous ulceration).

The following adverse reactions were reported in 77 dogs treated with CERENIA Injectable Solution and Tablets: Pain/vocalization upon injection, depression/lethargy, and injection site soreness in one dog treated with CERENIA Injectable Solution or Tablets. CERENIA Injectable Solution or Tablets were well tolerated in dogs presenting with various clinical conditions including gastroenteritis, gastritis, pancreatitis, enteritis, inflammatory bowel disease, anaemia, and hepatic disease.

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