TANOVEA™-CA1
(rabacfosadine for injection)

DOSAGE & ADMINISTRATION SUMMARY

TANOVEA™-CA1 is indicated for the treatment of lymphoma in dogs.

Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-475.

CAUTION: Federal (US) law restricts this drug to use by or on the order of a licensed veterinarian. Use only as directed. It is a violation of Federal Law to use this product other than as directed in the labeling.

Always provide the Client Information Sheet to the dog owner with each dose administration.

Administer TANOVEA-CA1 at 1 mg/kg body weight as a 30-minute intravenous infusion, once every three weeks, for up to five doses.

Stepwise dose reductions to 0.8 mg/kg and 0.66 mg/kg or dose delays may be used to manage adverse reactions.

TANOVEA-CA1 is supplied as a sterile lyophilized powder for reconstitution before use. After reconstitution with 2 mL 0.9% Sodium Chloride Injection, USP, the reconstituted solution contains 8.2 mg/mL of rabacfosadine.

Reconstitution and administration of TANOVEA-CA1

Wear chemotherapy resistant gloves, goggles, and protective clothing in the preparation and administration of TANOVEA-CA1. Use aseptic technique in the preparation and administration of TANOVEA-CA1.

Reconstitution instructions

1. Obtain the desired number of vials from the refrigerator.
2. Add 2 mL of 0.9% Sodium Chloride Injection, USP to the single-use vial.
3. Gently invert the vial several times until the drug has completely dissolved and the solution is particle free.
4. The solution should be clear without visible particulates. If particulates are observed, the solution should be discarded.

Dilution for infusion and administration instructions

1. TANOVEA-CA1 should be diluted for infusion within 4 hours of reconstitution.
2. Add the calculated volume of reconstituted TANOVEA-CA1 (8.2 mg/mL) to 0.9% Sodium Chloride Injection, USP in a polyvinyl chloride (PVC) infusion bag or polypropylene infusion syringe to yield a total infusion volume of 2 mL per kg body weight.
3. The volume to add should be calculated based on the exact weight of the dog. (See Table 1. for example doses and administration volumes).
4. The infusion solution should be used within 24 hours of being added to the infusion bag or syringe and within 4 hours of being added to an intravenous transfer set. Protection from light is not needed.
5. Administer TANOVEA-CA1 as a 30-minute intravenous infusion.

Table 1. Example doses and volumes. The dose to be administered should be calculated based on the exact weight of the dog. The table shows example doses and administration volumes at 1 mg/kg over 30 minutes.

Dog weight (kg)	Dog weight (lb)	Dose (mg)	Volume of reconstituted TANOVEA™ solution (mL)	Volume 0.9% NaCl (mL)	Total infusion volume (mL)	Rate of infusion (mL/minute)	No. of Vials
5	11	5	0.6	9.4	10	0.3	
10	22	10	1.2	18.8	20	0.7	1
15	33	15	1.8	28.2	30	1.0	
20	44	20	2.4	37.6	40	1.3	
25	55	25	3.0	47.0	50	1.7	2
30	66	30	3.7	56.3	60	2.0	
35	77	35	4.3	65.7	70	2.3	3
40	88	40	4.9	75.1	80	2.7	

TANOVEA-CA1 WAS GENERALLY WELL TOLERATED IN CLINICAL STUDIES. The majority of adverse reactions were Veterinary Cooperative Oncology Group (VCOG) grade 1 or 2. Most common adverse reactions included diarrhea, neutropenia, weight loss, hyporexia, and lethargy. Dermatologic changes, such as otitis externa, alopecia, dermatitis, pyoderma, ulcerations, and excoriations have also been observed. Less frequent but more serious adverse reactions included grade 3 anorexia/hyporexia, weight loss, vomiting, diarrhea, otitis externa, dehydration, aspiration pneumonia, neutropenia, thrombocytopenia, anemia, hyperbilirubinemia, and hypertriglyceridemia; grade 4 tachypnea and neutropenia; and grade 5 dyspnea (secondary to pulmonary fibrosis). Most adverse reactions resolved spontaneously, with supportive treatment, dose modification, or dose delay. **Contraindications, Warnings, and Precautions.** Do not use TANOVEA-CA1 in dogs with pulmonary fibrosis or a history of chronic pulmonary disease that could lead to fibrosis, such as chronic bronchitis. Do not use in West Highland White Terriers, and use with caution in other terrier breeds. Do not use in dogs that are pregnant, lactating, or intended for breeding. TANOVEA-CA1 has been associated with an infrequent, but potentially life-threatening or fatal pulmonary fibrosis, which may be an idiosyncratic toxicity. Monitoring for signs of pulmonary dysfunction and/or radiographic changes consistent with pulmonary fibrosis is recommended. TANOVEA-CA1 is not for use in humans and should be kept out of the reach of children. Wear chemotherapy-resistant gloves to prevent contact with feces, urine, vomit, and saliva of treated dogs for five days following treatment. TANOVEA-CA1 is cytotoxic and can cause birth defects, and affect female and male fertility. Pregnant and breast-feeding women should not prepare or administer the product. The safety and effectiveness of TANOVEA-CA1 has not been evaluated in conjunction with other chemotherapeutic agents or other treatments. The effect of concomitant medications on the metabolism of TANOVEA-CA1 has not been evaluated. ***Please see the TANOVEA-CA1 package insert for full prescribing information.***

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